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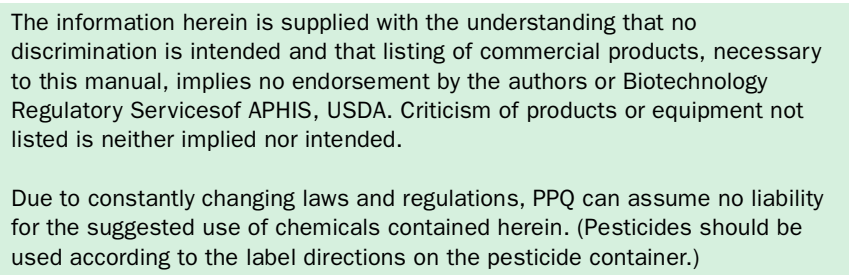
Animal and
Plant Health
Inspection
Service

Biotechnology
Regulatory Services

Biotechnology Manual

**Interim 2nd Edition Inspection Manual For Field Release Under Notification
Revision 01/2005-01**





Instructions:

1. Record the Transmittal Number and the date you received the update in the appropriate columns.
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Acknowledgements (Second edition)

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Introduction

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Overview

The manual was originated in the spring of 2000 by interested field officers and management seeking uniformity on how biotechnology field inspections should be conducted and reported. A draft version of the main section, *Inspection Guide for Notification Field Release*, was implemented by Regional Biotechnologists (RBT) and staff biotechnologists, and tested in the summer of 2000 by field officers and supervisors.

Additionally, there have been requests for an instruction manual to assist officers and supervisors with responsibilities to conduct notification field inspections. This need has increased significantly since notification inspections began in 1993, because the number of facilities and field sites continues to increase annually. The main section, *Inspection Guide for Biotechnology Notification Field Sites*, was revised to Portable Document Format (PDF) files. This edition advises that in August 2002, Biotechnology Regulatory Services (BRS) of APHIS was formed to replaced the Plant Protection and Quarantine's (PPQ's) Biotechnology Permit and Risk Assessment Unit of APHIS.

Authority

APHIS regulation 7CFR 340 was published in the Federal Register July 16, 1987, and extended the Federal Plant Pest Act to include genetically engineered organisms (GEO's) that are plant pests. From 1987 until 1993, field release, importation, or interstate movement of GEO's were based on applications through the APHS Permit Unit. On March 31, 1993, APHIS began a Notification process as an alternative to traditional Form 2000 permits. Notification expedited the regulation of frequently tested, thus familiar, plant material in the permit process without loss of biosafety for 6 major crops under 7CFR 340.3. The six crops were corn, cotton, potato, soybean, tobacco, and tomato.

Regulation 7CFR 340 was amended again on June 3, 1997, to include all plant species, in addition to the six crops listed above for Notification. However, to qualify for the Notification alternative, plants must be in accord with the eligibility requirements (7CFR 340.3(b)) and the performance standards (7CFR 340.3(c)) of the new rule.

In general, a notification or a permit must be completed and approved for applicants who seek to import, move interstate, or release into the environment, genetically engineered organisms derived from a plant pest, virus, or organisms of unknown pest status.

Inspection of biotechnology notification field release sites, permit field release sites, or permit movement facilities, is conducted by PPQ field work units and state cooperator under the direction of BRS.

Scope

The manual provides background and information on the biotechnology permit program and inspections. It is divided into sections on introduction, purpose, procedure, training, references, and an appendix. It assists the officer in planning for inspections, becoming familiar essential documentation, and encouraging use of the BRS Web site and other educational resources in this rapidly advancing area of science.

There are currently two types of biotechnology field sites; 1) notification field release sites; and 2) permit field release sites. In addition, permit movement or importation requests may require a facility site inspection. Emphasis in this manual was placed on biotechnology notification field release site inspection because these have comprised most of the total biotechnology inspections nationally for the last 11 years. The approach for permit inspection is similar to notification field site inspections, with one notable exception in identifying performance standards. The protocol to meet performance standards for a field test under permit can be found by the inspector **in the permit application**. Performance standards for field test under notification are requested from the responsible person for the field test (See Procedure Section).

The "Procedure Section" contains essential material for notification site inspection and reporting. Information on biotechnology permit field releases is given in the "Procedure Section" under "Background to Field Release Under Notification." The Appendix also includes essential permit and reporting documents pursuant to Form 2000 including permit conditions, supplemental conditions, and standard conditions. These materials provide background for the inspecting

officer. New or inexperienced officers may not be familiar with these materials because they are not requested as frequently as Notification inspections.

Only a few transgenic arthropod permits have been issued, but this is anticipated to increase.

The second edition of the manual is in PDF format and includes an updated notification worksheet, traditional planting and harvest permit worksheets, and adds 5 new pharmaceutical-industrial permit worksheets due to the Federal Register Notice of March 10, 2003. Also, the manual includes an updated Facility Inspection Checklist, new Storage Inspection Checklist, and Table of Important Reporting Events in the Appendix. Sample pages of permit conditions and supporting information have been updated. An inspection worksheet for transgenic arthropods is in development by BRS.

Users

This manual is intended for PPQ officers, BRS Cooperators, and supervisors responsible for inspections of biotechnology field sites. To make best use of the manual, officers should read it and become thoroughly familiar with the reporting documents before contacting a researcher or cooperator to schedule an inspection. Information presented can be comprehended if carefully read by new officers.

Time Sensitivity

Notification inspections may be scheduled at any time during the planting year. However, the Notification Inspection Guide points out that the ideal time to schedule an inspection is prior to planting, flowering time, or harvest of the crop. This arrangement allows the inspector to see if containment is being followed and also gives a view of surrounding crops. It is important to determine if sexually compatible crops or weeds are growing too close to the permit site. Based on crop material grown under auspices of a permit, timing of inspections would be ideally conducted near flowering for the reasons explained for notification. However, later in the season, near harvest, inspection can also be important.

Although field site inspections under notification may be scheduled at any time during the year, facility inspections are time sensitive. Timing of facility inspections is important because live plant material may be on mailing delay pending inspection. Unnecessary delays expose the APHIS to negligence and legal action. Also, the officer should be mindful of the requested deadline for the inspection by the RBT. A facility inspection must be completed within 60 working days from the

time the permit application is received by BRS, according to regulation 7CFR 340. Officers should attempt to expedite these inspections by simultaneously inviting a representative from the State Department of Agriculture to attend the inspection on a date mutually acceptable to all parties.

Role of the Inspector

The inspector's role in biotechnology inspections consists of the following:

- ◆ making observations at the inspection site
- ◆ documenting those observations completely and concisely
- ◆ collecting any supporting evidence, such as photos and maps

This information will become your inspection report. BRS Compliance and Enforcement Staff will assess your reports and make the final determination about violations and the compliance status of the inspected site. If you observe a situation that may require immediate intervention contact you BRS Regional Biotechnologist (RBT) for assistance.

All signed inspection reports and especially those that include infractions and or violations are internal APHIS, BRS documents.

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Biotechnology Manual

Purpose

The manual is for instruction and reference by officers with biotechnology responsibilities as follows:

- ◆ Conducting field inspections pursuant to notification and Form 2000.
- ◆ Completing appropriate reports and associated permit inspection checklists, worksheets, and other relevant documents.
- ◆ Having familiarity with permit conditions (see Appendices for Standard and Supplemental Permit Conditions).
- ◆ Interpreting field site conditions and determining if the site or facility is in compliance.
- ◆ Educating researchers, cooperators, and the public to enhance self-compliance.
- ◆ Increasing awareness of the permit biotechnology process.
- ◆ Introducing officers to the APHIS Biotechnology Home Page and associated educational reference material.
- ◆ Having familiarity with how to treat confidential business information (CBI) in communications with state, public, and others. This includes keeping CBI training up to date, which is initiated by BRS.
- ◆ Learning frequently used terms of notifications and biotechnology permits.
- ◆ Enforcing APHIS biotechnology regulations.
- ◆ Developing self-compliance with permittees and cooperators.
- ◆ Serve as a reference source for future questions and concerns.

Purpose

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Manual

Procedures

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Background to Field Releases Under Notification	page-3-1
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Background to Field Releases Under Notification

There is no substitute for a good field site inspection to determine if the permittee is in compliance. In addition, our mission is to educate the permittee and cooperator to use self-compliance and to reduce the need for continuous inspection.

To initiate a biotechnology inspection, the Compliance and Enforcement Branch of Biotechnology Regulatory Services (BRS) issues an Inspection Authorization Number (IAN) and sends a request for an inspection of that specific field site(s) to the BRS Regional Biotechnologist (RBT). The BRS RBT sends the inspection request to the Plant Protection and Quarantine (PPQ) Regional Biotechnologist (RBT). The PPQ RBT coordinates inspection requests with PPQ State Plant Health Directors (SPHDs) and State Cooperators to schedule the inspection. Reports of all biotech inspections are written by the inspector on checklists or worksheets in PDF format and electronically transmitted to the PPQ and BRS Regional Biotechnologist (RBT) within 5 to 7 days of the inspection. The RBTs will concurrently and immediately review the worksheets and make corrections as needed and advise the inspector if the worksheets are incomplete or need revision. The review should take 3 to 5 days. Once the worksheets are reviewed and deemed correct, the inspector dates the hardcopy of the worksheet with the date it was approved. Then, the inspector signs and dates the worksheet and sends it to the BRS Compliance and Enforcement Branch. The time from inspection completion to the receipt of the final signed report by the BRS Compliance Branch Chief should be near the goal of 10 working days. (See [Figure 3-1 on page-3-3](#)). In contrast to notification inspections for lower risk field releases, inspectors occasionally inspect permitted plant material under biotechnology permits. Using Form 2000 as a guide, these biotechnology permits have higher risk and involve a joint effort with State Departments of Agriculture. Biotechnology permits and

Procedures

Background to Field Releases Under Notification

notifications may involve importation, interstate movement, multiple years and locations. Only permits will include insects, arthropods, animals, or pharmaceutical and industrial crops. The inspector will be furnished with special instructions and reporting format during some types of permit inspections, such as those including insects, arthropods, animals, or pharmaceutical and industrial crops. The inspector should invite a representative from the State department of agriculture to be present at the inspection. Also, if a facility inspection is part of the permit review process, it is advisable it is advisable to have the permittee invite the greenhouse manager (if a greenhouse is part of the inspection) and a Biosafety Officer to be present. This cannot be overemphasized at a university and all other kinds of facilities that may have a laboratory, greenhouse, and growth chamber. Worksheets and permit forms for all other non-notification field trials are included in the manual Appendix. Arthropod GEO's are not included.

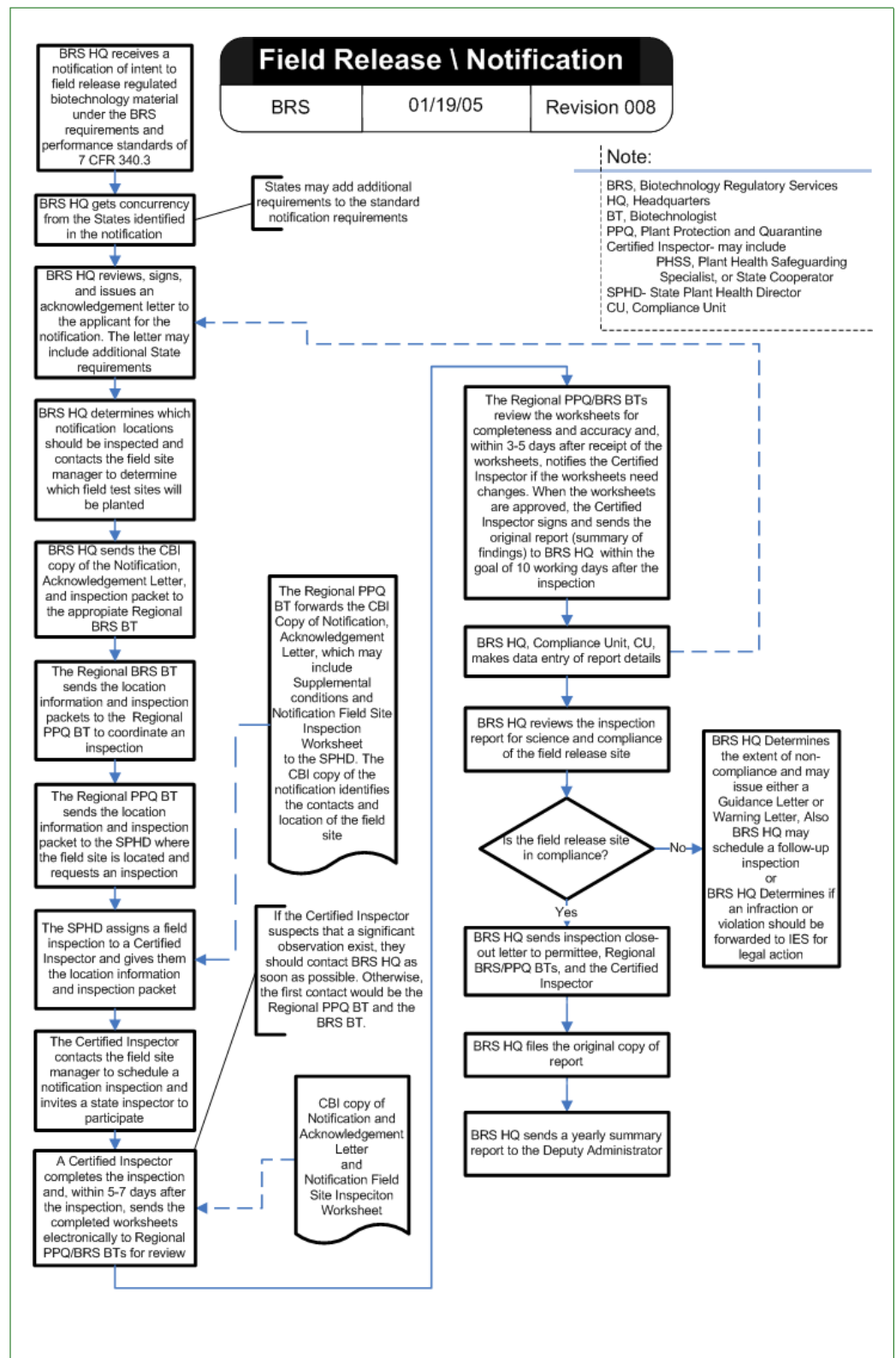


FIGURE 3-1 : Workflow for Inspection of Field Release Sites Under Notification

All signed field inspection reports are internal APHIS, BRS documents prepared for BRS. If the permittee (or Permit applicant) wants to obtain a copy of the inspection report, they must send (not fax or e-mail) a written request that includes the permit number to:

Deputy Administrator
USDA, APHIS, BRS
4700 River Road, Unit 147
Riverdale, Maryland 20737

An APHIS biotechnology permit does not exempt, nor supersede, GEO's from quarantines required by other Federal regulations (for example, the pink bollworm quarantine in Arizona, certain regulated counties in California) or from special conditions required by State Departments of Agriculture.

Additionally, special field inspections are conducted by biotechnologists from the BRS, but these are mainly for field releases of plants with genes that express pharmaceutical or industrial products.

Inspectors should have a field kit with essential tools for inspection. This kit should include, but is not limited to: a GIS/GPS unit, digital camera, worksheets, laser range finder, etc. Also, it is recommended that an inspector have a cell phone and first-aid kit for emergencies. The inspector must read permit or notification material prior to an inspection.

Confidential business information (CBI) such as location of field sites, must be protected from unauthorized disclosure at all times. The inspection worksheet, summary report, and all related documentation from an inspection is assumed to contain CBI, and should be treated as such. All inspectors are to have received training on CBI prior to undertaking inspections for BRS.

All notifications receive a risk score based on several parameters including the applicant's compliance history, the total acreage planted, the number of field trial sites and states involved, and whether the applicant is new. Notifications are ranked by risk score; those receiving higher scores are considered a higher risk and will be targeted for inspection. Special considerations or circumstances may warrant inspecting a Notification regardless of its risk score.

Notifications usually receive only one inspection per growing season unless evidence of noncompliance exists. Follow up inspections will be directed by the BRS Compliance and Enforcement Branch and will request that you focus on specific problems/issues discovered during the initial inspection.

Preparing for Site Inspections

The purpose of inspections for field tests under notification is to determine if the applicants have the means to accomplish the performance standards and are following them. See **Table 3-2 on page-3-1-5** for a summary of step necessary to complete your field inspection.

Preparing for Site Inspections

1. Check Site Location and Confirm Request **page-3-5**
2. Validate the Location and Size of the Field Site **page-3-8**
3. Schedule the Inspection **page-3-6**
4. Check Inspection Equipment **page-3-7**

Conducting the Inspection

1. Validate the Location and Size of the Field Site **page-3-8**
2. Meet with the On-site Manager **page-3-8**
3. Complete the Notification Inspection Worksheet and Make Observations **page-3-8**

Reporting Inspection Results

1. Complete the Inspection Report and Send it to Your BRS Regional Biotechnologist **page-3-12**

FIGURE 3-2 Summary of Steps for Field Site Inspections Under Notification

Receiving an Inspection Request

Step 1—Check Site Location and Confirm Request

When you receive a request from the SPHD to inspect a field test site under notification, confirm that the inspection site is located within your jurisdiction. Also, confirm with the SPHD that you have received instructions and you are able to conduct the biotechnology inspection. Coordinate logistics for the inspection with the SPHD to maximize time and resources.

If you are requested to inspect more than one site, identify all the sites that you can inspect in a single trip. Prioritize these sites and start to develop your inspection schedule.

Step 2—Validate Documentation

Confirm that the documents you need for inspection are available and complete. Make sure you have the following documents:

- ◆ Official Acknowledgement Letter for the Notification
- ◆ Current Notification Inspection Worksheets
- ◆ Current copy of performance standards (7 CFR 340.3(c))
- ◆ Copy of applicant's protocols used to achieve performance standards for the field test site
- ◆ Copy of applicant's Supplemental Conditions (if any)

◆ Current Copy of the Biotechnology Manual



The documentation that you use for inspection should be the CBI copy. Always safeguard CBI material and establish credentials with anyone involved with the inspection.

Contacting the Inspection Participants

Step 3—Schedule the Inspection

Ask the applicant for times of anticipated planting, flowering (if any), harvesting (if any), and termination of the field test. Arrange the field site inspection **after planting has occurred**, preferably when the plants normally would be flowering or during harvest. Also, ask the applicant for the following:

- ◆ Specific date, time and driving directions to meet at the field trial location for the inspection
- ◆ Number and size of field trial sites at the field trial location, and their general proximity to the initial meeting location
- ◆ Pesticide applications at the field site
- ◆ Unusual road or field conditions (e.g., flooded field site or road construction)

Go to <http://www.aphis.usda.gov/brs/index.html> for additional details.

It will not be possible to read the all the notification documentation while the inspection is in progress. Therefore, **review these documents before the inspection.**

Inform the applicant that you will ask for evidence during the inspection that the applicant has the capability/materials to meet or to have met all of their protocols (e.g., shipping container, field tags, devitalization devices, etc.).

You may meet with the applicant's cooperator rather than the applicant at the field site. Remind the applicant that it is his or her responsibility to ensure that the cooperator understands and can answer questions about the applicant's site-specific protocols to meet the performance standards during the inspection. This is an opportunity to educate for self-compliance.

When you have a specific date scheduled for the inspection, contact the appropriate State agricultural officials to participate in the inspection.

If you have questions before or during the inspection, make a note and contact the Regional Biotechnologist for consultation.

Some specific questions to be addressed by the inspectors regarding the applicant's protocols are listed in **bold-type** in the following section on performance standards.

Selecting Your Inspection Equipment

Step 4—Check Inspection Equipment

Confirm that you have the necessary equipment to conduct the inspection at the sites you select. This equipment should be in good working order and may include the following:

- ◆ Hard hat
- ◆ First-aid kit
- ◆ Safety glasses
- ◆ Safety shoes
- ◆ Coveralls
- ◆ Gloves
- ◆ Communication device (cell phone)
- ◆ Safety briefing for relative equipment
- ◆ Flashlight
- ◆ Clipboard
- ◆ Current Notification Inspection Worksheet
- ◆ Inventory labels
- ◆ Tape measure
- ◆ Measuring wheel or laser range finder
- ◆ Digital camera ([See “Making a Photographic Record” on page-3-1-9](#))
- ◆ Manufactures' equipment manual (and maybe factory representative)
- ◆ Sunscreen
- ◆ GPS device
- ◆ Compass

Conducting the Inspection

Arriving at the Site

Step 1— Validate the Location and Size of the Field Site

Validate the location of the site with GPS readings. Assure that the coordinates are noted on a paper map if it exist. Record at least one GPS reading at a corner of the plot and designate which corner. If possible, get a GPS reading at all corners. If possible, use a laser range finder or measuring wheel to measure the site.

Step 2— Meet with the On-site Manager

Meet with the on-site manager to answer questions and validate the site's compliance to performance standards, and any supplemental conditions

Gathering and Recording Site Information

Step 3— Complete the Notification Inspection Worksheet and Make Observations

Complete the Notification Inspection Worksheet and document what you see with photos (digital pictures) Also, refer to the Performance Standards Section for additional information needed to complete the Notification Inspection Worksheet. (See **“Guidance for Completing the Notification Inspection Worksheet and Summary of Findings” on page-3-1-16** and See **“Guidance to Performance Standards” on page-3-1-42**)

Also make the following observations:

- ◆ Accuracy of required isolation distances (See following table of isolation distances)
- ◆ Accuracy of field plot design and size
- ◆ Accuracy of records
- ◆ General condition of crop
- ◆ Special practices, such keeping transgenic plants in cages prior to flowering
- ◆ Disposal of plant material
- ◆ Compliance of shipping containers (if applicable)
- ◆ Compliance of treatment procedures
- ◆ Potential violations



Do not inadvertently carry transgenic plant material outside the controlled area. If you leave a test site and travel to an area where sexually compatible plants exist or transgenic material may propagate, you could compromise the containment of the transgenic material (especially during pollination). Make sure your clothes and vehicle are free of transgenic material before you leave the test site.

Making a Photographic Record

Photos taken during an inspection are an effective and useful form of documentation, and may be used as evidence in the event of a violation. In this section, we review the purpose of taking photographs during an inspection, subjects to consider during those inspections, methods for preparing and maintaining digital photographs, and how to address requests made by organizations regarding photographs taken during an inspection.

Photographs provide the agency with the evidence to clearly verify the authenticity of the conditions described in your inspection report.

Photographs included in your inspection report should be limited to significant observations that are described in your report. You must create a trail, starting with the taking of the photo, confirming its original accuracy and establishing a record describing the chain of custody. To do this, you must describe each photograph in your “Summary of Findings” in sufficient detail to assure positive correlation of the photo with your inspection findings. One way you can do this is to photograph a card with your name, district address and phone numbers as the first picture in the digital record. This will help identify the file series and assist in tracking if it is lost or becomes separated from the file during processing or storage. Proper procedures will also allow the agency to provide evidence confirming the authenticity of the photograph in the event you are not able to testify personally.

Requesting Permission to Take Photographs

Do **not** request permission from the responsible party to take photographs during an inspection. Take your camera into the field, farmstead, and buildings and use it as necessary just as you use other inspection equipment.

If the responsible party objects to taking photographs, casually explain that photos are an integral part of an inspection, present an accurate picture of production conditions, and are maintained as confidential business information (CBI). Only if necessary, advise the responsible party the U.S. Courts have held that photographs may lawfully be taken as part of an inspection; supporting judicial cases can be provided if necessary.

If the responsible party refuses, advise your supervisor so legal remedies may be sought to allow you to take photographs, if appropriate. If you have already taken some photos do not surrender these photographs to the responsible party. Advise the organization that it can obtain copies of the photos under the Freedom of Information Act through APHIS Legislative and Public Affairs (LPA). Do not routinely advise organizations they may have copies of photographs that are part of their report.

Selecting Photographic Subjects

There are a several photographic subjects that are important for the types of violations that occur under notifications. Examples of practices effectively documented by photographs include:

- ◆ Items
 - ❖ Packaging or containers used for shipment or movement
 - ❖ Labels on shipping containers that show proper shipping procedures
 - ❖ Identification tags on plants or containers that demonstrate identification procedures
 - ❖ Markers that are used to delineate the boundaries of the field trial site
 - ❖ Materials, such as fences or traps, used to prevent human or animal incursion on to the field trial site
 - ❖ Devitalization equipment, such as mills or incinerators
- ◆ Locations
 - ❖ All of the field sites in the field trial location
 - ❖ Border rows or fallow zones
 - ❖ Maps or drawings that were used on site
 - ❖ The staging area or station where cleaning, filling and emptying of equipment takes place
 - ❖ The area between the field trial site and the nearest cultivated planting of a related species
- ◆ Processes
 - ❖ Cleaning process underway on planting, mowing or harvesting equipment
 - ❖ Flower removal or bagging processes
 - ❖ Planting or harvesting operations
 - ❖ Devitalization operations
 - ❖ Post harvest operations (volunteer removal)

Preparing and maintaining Digital Photographs.

All photos taken should be done in a digital format, unless a digital camera is unavailable. Use high resolution format when taking digital photos, particularly when photographing landscapes, documents, and labels.

When photographing labels, make sure that your picture will result in a legible label with print large enough to be read by an unaided eye.

**Protecting
Evidence and
Maintaining
Chain of
Custody**

Take photographs in such a way as to demonstrate the size and scale of the object or landscape being photographed. For example, the distance between two fields may be better represented by placing an object, such as a vehicle, into the photo frame. For smaller scale photographs, place a wallet or coin in the photo for size reference, as applicable.

A digital photo's chain of custody (and authenticity) must be assured and protected with the following procedures:

- ◆ Check camera for initial settings
 - ❖ Prior to using the digital camera, verify the date and time stamp is correct and there are no images stored on the memory media.
- ◆ Secure evidence
 - ❖ The camera and the storage media used must be handled in a manner to protect your evidence and may be the trail of the "chain of custody" for the evidence you collect. For example: The camera and storage media must be in the inspector's personal possession at all times and held under lock/key in a secure storage area. Any additional storage media with images shall also remain in the inspector's personal possession until transferred to permanent storage media. Where necessary, document these factors in your notes or written report.
- ◆ Take high resolution photographs
 - ❖ Take photographs using a high resolution setting, while still allowing enough digital memory to take enough photographs for the inspection.

- ◆ Create a master of digital photographs, as soon as practical, using the following guidelines:
 - ❖ The files should not be compressed during the download or file saving process, so that maximum resolution can be transferred into storage.
 - ❖ Confirm that the computer has the current time and date settings prior to file transfer, and make certain that the time/date stamp on the photos is correct, and that the downloaded files are not corrupted, prior to erasing photos from the camera's digital media storage.
 - ❖ Floppy disks or compact discs (in CD-R format) should generally be used to capture the photograph and subsequent copies of the original file.
 - ❖ Save files on digital media as write-protected
 - ❖ Identify with a label with the APHIS Inspection Number, date taken, your initials, and as an original image record (The APHIS Inspection Number is assigned by BRS and recorded on the Notification Inspection Worksheet).
 - ❖ Seal digital media in an official USDA envelope marked with the letters, "PROTECT FROM MAGNETIC FIELDS, BENDING, OR SCRATCHING"
 - ❖ Document in your report the verification and identification of each photographic image comparing them to your notes, which were recorded at the time the photographs were taken.

Reporting Inspection Results



Generally, your contact for field site inspection information is the PPQ Regional Biotechnologist (RBT). However, if you suspect a potential violation at a field trial site, contact the BRS Compliance and Enforcement Branch in Riverdale, MD, and also notify the RBT.

Step 1—Complete the Inspection Report and Send it to Your BRS Regional Biotechnologist

Reports of all biotech inspections are written by the inspector on checklists or worksheets in the format provided by BRS (PDF or MS Word format) and electronically transmitted to the PPQ and BRS Regional Biotechnologist (RBT) within 5 to 7 days of the inspection. The RBTs will concurrently and immediately review the worksheets and make corrections as needed and advise the inspector if the worksheets are incomplete or need revision. The review should take 3 to 5 days. Once the worksheets are reviewed and deemed correct, the inspector dates the hardcopy of the worksheet with the date it was

approved. Then, the inspector signs and dates the worksheet and sends it with the supporting documentation to the BRS Compliance and Enforcement Branch. The time from inspection completion to the receipt of the final signed report by the BRS Compliance Branch Chief should be near the goal of 10 working days.

No cover letter is necessary to send the report to BRS because all needed information is on the worksheet.



Reports with your original signatures must be sent to the BRS Compliance Branch Chief.

The complete Inspection Report (IR) submitted to the BRS Compliance and Enforcement Branch should include the following items:

- ◆ Completed worksheet(s);
- ◆ Summary of Findings (see below);
- ◆ Photographs of significant observations referenced in the report
- ◆ Maps; drawings; charts; other materials.

The IR must be factual, concise, and provide a clear picture of the inspection.

A bound, field notebook or other method should be used for recording sufficient, detailed inspection notes to accurately describe what is taking place at the site. Although these notes are not a formal part of your report, they will provide the basis for preparing the Summary of Findings report. **Do not write your notes on the inspection worksheet. The worksheet should only contain your check marks.** The following types of information may be included in the field notebook:

- ◆ Observations-record all conditions, practices, unusual problems, and other observations that support your findings
- ◆ Overview of any potential violations that are submitted to the Compliance and Enforcement Branch (and RBT)
- ◆ General information-include the names and titles of personnel participating in the inspection and those providing information during the inspection

Summary of Findings

This is the narrative part of the IR and provides details about the inspector's observations and findings. Use the information provided for each question in the "Worksheet Guidelines" to guide and assist you with your narrative. Your response should contain sufficient detail so that BRS staff reading the report will clearly understand the observation(s) and will be able to assess the facility's compliance with regulations. Your report is critical and will be used by BRS to support any follow-up regulatory actions. BRS will also use the reports to send a closeout letter to the responsible party describing the results of inspections including those where there were no deviations from the regulations or significant problems. The narrative should include the following observations:

- ◆ An explanation for all worksheet observations that are marked "No" and any other observations that you feel require additional details.
- ◆ Describe any corrective actions promised or implemented for worksheet items marked "No". Include the time frames given for future corrections and possible dates for follow-up inspections.
- ◆ Record all significant observations regardless of corrective actions implemented during the inspection.
- ◆ Describe any reportable incidents you discovered that the responsible party failed to report to BRS.
- ◆ Describe any responses or objections to your observations provided by the responsible parties. Do not debate your observations with the responsible party. The Compliance and Enforcement Branch will determine the validity of their objections.
- ◆ Include the names of individuals providing relevant information if multiple individuals (i.e. company officials and cooperators/investigators) are participating in the inspection.
- ◆ Cross-reference any photographs, maps, or other exhibits you included in the IR.
- ◆ Describe any other concerns you have about the responsible party's ability to meet the performance standards related to packing, shipping, and transportation; identification and segregation; devitalization; storage; equipment cleaning; growth and maintenance in approved areas; and monitoring/managing the trial sites next year.

- ◆ If this is a follow up inspection, describe the improvements initiated by the responsible party and corrective actions taken in response to BRS correspondence directing them to implement corrective actions.

EXAMPLE: Here is an example of an inspector's observation provided for the following worksheet question:

No.	Question	Yes	No	N/A
17.	Is the area within the isolation distance for the regulated article field trial site(s) (the fallow zone) free of sexually compatible plant species ?		X	

Observation- "Except for one of the four field trials sites (WS/4), the sites were planted into a pivot area that had been planted to corn in 2003. The corn that I observed in the fallow zone around the field trial site during planting on May 19, 2004, almost certainly was volunteer corn from that previous year's crop. The volunteers were at the 2nd or 3rd leaf growth stage. I commented to the field personnel that sexually compatible volunteers were present and must be controlled."

Photographs, maps, drawings, charts, and other Materials

Submit the original photographs, maps, drawings, charts and other materials in your report to USDA APHIS BRS. Your report must include a listing of the all attached documents or photographs submitted. The listed attachments should be described on the second page of the worksheet. All documents or photos listed must include:


- ◆ File or document names
- ◆ Date and time received
- ◆ Brief description of each file or document's subject matter

When you sign the inspection report and submit the photographs and documents with your report, your signature certifies that you are saying that the report, including any attachments, is original and accurate to the best of your ability. The original inspection report and attachments may be used in subsequent litigation; so, always maintain a chain of custody when you submit your report.

If you need to use copies of documents or files from the investigation in the future, you must only use a copy of the original in subsequent manipulations (such as cropping).

Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

In the following sections, each of the questions posed in the Notification Inspection Worksheet are addressed in the order that you will encounter them on the worksheet. (See **Figure 3-3 on page-3-17**). Also, refer to the Performance Standards Section for additional information needed to complete the Notification Inspection Worksheet. (See **“Guidance to Performance Standards” on page-3-1-42**)




Worksheet 001: NOTIFICATION INSPECTION WORKSHEET

A. BRS Inspection Authorization Number	B. Notification Number
C. Inspector name & title	D. Inspector phone
E. Inspector location	F. Notification holder
G. Cooperator at site	H. Cooperator phone
I. Name(s) of staff in planting	J. General location
K. Field trial site GPS coordinates	
At two front corners:	Any additional coordinates:
1.	
2.	
L. Inspection date	M. Inspection start time

Provide the answers below. If the answer to any questions is "no" or could not be answered at the time of the inspection, explain these in a cover letter submitted with this report to the Biotechnology Regional Manager.

No.	Question	Yes	No	NA
1.	Does the notification you received from BRS match exactly the one held by the responsible party on site?			
2.	Do the shipping and packing containers used for this field trial meet the performance standards?			
3.	Were packing and shipping materials used for this field trial cleaned out and disposed of to meet performance standards?			
4.	Were transport or storage containers employed so as to fully contain the regulated article at the field trial location?			
5.	Do descriptions or records demonstrate that equipment used in this field trial was cleaned so as to meet performance standards?			
6.	Did the responsible party maintain identity of the regulated article at all times during handling and growing (seed storage, planting/harvest, etc.)?			
7.	Are there written records or descriptions showing that equipment and cleaning areas used in this field trial are, or will be, treated so as to devitalize the regulated article?			



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FIGURE 3-3: CE Worksheet 001: Notification Inspection Worksheet, page 1 of 5

Procedures


Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

Worksheet 001: Notification Inspection

BRS IAN: _____

No.	Question	Yes	No	NA
8.	Did the notification holder provide you with an up-to-date map of sufficient detail showing the field site(s) for regulated articles under this notification?			
9.	Is the total area of the field site(s) at or below the total amount of acreage approved in the notification record?			
10.	Are the type(s) of regulated article(s) in field trials at location (organism/trait) exactly and only those stated in the notification?			
11.	If border rows are present in the field trial site, are they grown so as to meet performance standards?			
12.	Are measures being employed as to minimize or prevent expected human or animal incursion onto the field trial?			
13.	If flower removal was used to control reproduction, was it employed successfully?			
14.	If flower bagging was used to control reproduction, was it employed successfully?			
15.	If border rows were used to control reproduction, were they employed successfully?			
16.	If temporal isolation (flowering time) was used to control reproduction, was it employed successfully?			
17.	Is the area within the isolation distance for the regulated article field trial site free of sexually compatible plant species ?			
18.	Does the notification holder have a description or records for monitoring volunteers for these field trial site(s) next year?			
19.	Do descriptions or records demonstrate that the responsible party is monitoring for any deleterious effects by regulated article on itself, other plants, non-target organisms, or the environment?			

Name and description of any files or documents attached to worksheet:



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FIGURE 3-4: CE Worksheet 001: Notification Inspection Worksheet, page 2 of 5

FIGURE 3-5: CE Worksheet 001: Notification Inspection Worksheet, page 3 of 5

Procedures

Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

Worksheet 001: Notification Inspection

BRS IAN: _____

SUMMARY OF FINDINGS (cont.)

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FIGURE 3-6: CE Worksheet 001: Notification Inspection Worksheet, page 4 of 5


Worksheet 001: Notification Inspection	BRS IAN: _____				
<p>Completion:</p> <p>Check here if the inspection was not completed <input type="checkbox"/></p> <p>Reason for cancellation of the inspection: _____</p> <p>_____</p> <p>_____</p>					
<p>Worksheet Submission Information:</p> <p>This report was submitted to the BRS Regional Biotechnologist and approved on (date) _____.</p> <p>This report with original signature was then furnished to BRS and I certify that this report, submitted on (date) _____, is true and accurate to the best of my knowledge (Inspecting Officer Signature) _____.</p> <p>Please fax or email the completed worksheet to your BRS Regional Biotechnologist at one of these two addresses:</p> <table style="width: 100%; border: none;"> <tr> <td style="vertical-align: top; width: 50%;"> <p>Ralph Stoaks BRS Western Regional Biotechnologist 2150 Centre Avenue, Bldg. B-3E10 Fort Collins, CO 80526 Fax: (970) 494-7576 Ralph.D.Stoaks@aphis.usda.gov</p> </td> <td style="vertical-align: top; width: 50%;"> <p>Roger Holman PPQ Eastern Regional Biotechnologist 920 Main Campus Raleigh, NC 27606 Fax: 919-855-7319 Roger.L.Holman@aphis.usda.gov</p> </td> </tr> <tr> <td colspan="2" style="vertical-align: top; padding-top: 10px;"> <p>Stuart W. Kuehn PPQ Western Regional Program Manager 2150 Centre Avenue, Bldg. B, 3E10 Fort Collins, CO 80526 Fax: 970-494-7501 Stuart.W.Kuehn@aphis.usda.gov</p> </td> </tr> </table> <p>Once approved by the BRS Regional Biotechnologist, please mail completed worksheet to BRS Headquarters at:</p> <p style="margin-left: 40px;">Compliance & Enforcement Branch USDA APHIS BRS 4700 River Rd., Unit 147 Riverdale, MD 20737</p>		<p>Ralph Stoaks BRS Western Regional Biotechnologist 2150 Centre Avenue, Bldg. B-3E10 Fort Collins, CO 80526 Fax: (970) 494-7576 Ralph.D.Stoaks@aphis.usda.gov</p>	<p>Roger Holman PPQ Eastern Regional Biotechnologist 920 Main Campus Raleigh, NC 27606 Fax: 919-855-7319 Roger.L.Holman@aphis.usda.gov</p>	<p>Stuart W. Kuehn PPQ Western Regional Program Manager 2150 Centre Avenue, Bldg. B, 3E10 Fort Collins, CO 80526 Fax: 970-494-7501 Stuart.W.Kuehn@aphis.usda.gov</p>	
<p>Ralph Stoaks BRS Western Regional Biotechnologist 2150 Centre Avenue, Bldg. B-3E10 Fort Collins, CO 80526 Fax: (970) 494-7576 Ralph.D.Stoaks@aphis.usda.gov</p>	<p>Roger Holman PPQ Eastern Regional Biotechnologist 920 Main Campus Raleigh, NC 27606 Fax: 919-855-7319 Roger.L.Holman@aphis.usda.gov</p>				
<p>Stuart W. Kuehn PPQ Western Regional Program Manager 2150 Centre Avenue, Bldg. B, 3E10 Fort Collins, CO 80526 Fax: 970-494-7501 Stuart.W.Kuehn@aphis.usda.gov</p>					
<div style="display: flex; justify-content: space-between; align-items: center;"> <div style="text-align: center;">  <p style="font-size: small;">Safeguarding American Agriculture APHIS is an agency of the USDA's Marketing and Regulatory Program An Equal Opportunity Provider and Employer</p> </div> <div style="text-align: right; font-size: x-small;"> <p><i>This record contains confidential business information</i></p> <p>Page 5 of 5 Document version 01/19/05</p> </div> </div>					

FIGURE 3-7: CE Worksheet 001: Notification Inspection Worksheet, page 5 of 5

The first section addresses the information requested at the top of the worksheet (Page 1, A through M). The information requested in this section is critical for proper identification of the regulated article, the parties responsible for managing the regulated article on site, and to verify that the regulated article is being grown using a valid, complete and accurate notification record.

The second section provides guidance on each of the worksheet questions in sequential order (Pages 1-2, Questions 1-18). Each of these questions follows the excerpt from the Code of Federal Regulations on which it is based.

Information Section of Notification Inspection Worksheet

A. BRS Inspection Authorization Number (IAN)— On the first page of the Notification Inspection Worksheet, record the BRS Inspection Authorization Number (BRS IAN). The BRS IAN is found on the Inspection Authorization Cover Sheet. Write the BRS IAN on every worksheet that follows, and any additional documentation that you submit for this inspection. Maps, photographs, and other paper documents should include the BRS IAN on them. The IAN is the only number that will make it possible to locate and file all of the different records for this inspection, should the pages become separated.

Although you may routinely monitor locations that require regulatory oversight, do not spontaneously conduct a formal biotechnology inspection without a BRS Inspection Authorization Number. However, spontaneous inspections should occur only if there is an emergency, if you suspect that an organization is in non-compliance with federal regulations, or if there is uncertainty about the location and nature of the site once you are in the field.

If you feel that an inspection is warranted because you suspect or observe non-compliance with federal regulations, first, attempt to contact the BRS Regional Biotechnologist to obtain an IAN while in the field. If you are unable to obtain a BRS IAN but suspect non-compliance, undertake the inspection and obtain a BRS IAN number for the case afterwards. Remember to put the BRS IAN on all documents related to your inspection upon receiving it.

Proximity of field trials to one another is **not** a sufficient reason to expand the scope of your inspection. Inspections conducted without an IAN should not be charged to BRS or to PPQ's biotechnology accounting code.

If you have questions about the number of locations and field sites within the scope of a given BRS IAN, please contact the BRS Regional Biotechnologist to further clarify the scope of the authorized inspection.

Every BRS IAN that has been authorized should result in a report to BRS, including those inspections that you could not complete. Send a written explanation for any incomplete inspections to your BRS Regional Biotechnologist.

B. Notification Number —Record the Notification Number. The Notification Number is the reference number for the notification that was reviewed by APHIS BRS and approved for planting. When an organization receives approval to plant based on a notification process, the notifications are considered “acknowledged” by APHIS BRS, and a formal letter of acknowledgement is sent to the applicant.

Notification reference numbers are based on the date the BRS Permit Staff acknowledge the notification. Notifications are identified separately from permits by the letter “n” following the 7-digit code.

The notification reference number should be provided to you in advance, along with copies of the paperwork from APHIS headquarters that describe basic information you need for initiating the inspection.

It is important that you determine with certainty that the notification you are inspecting is valid. A valid notification must include a signed, completed Acknowledgement Letter (AL) from APHIS BRS headquarters. A valid AL should describe:

- ◆ The Notification (Reference) Number
- ◆ Name of the Regulated Article
- ◆ Destination of the field trial
- ◆ Applicant/Responsible Party contact information
- ◆ Duration of the field trial

The AL must be signed by the Regulatory Permit Specialist at APHIS BRS. Without a signature by this authority, the notification is not valid.

There are several aspects to notifications that are important to keep in mind:

- ◆ Notifications are usually approved for only one calendar year, the year of planting. There may be exceptions, particularly for perennial species. This information is provided in the AL.
- ◆ There are many plantings done year after year that have different notification numbers, as applicants reapply annually. You must inspect using only the notification information valid in the year of the field trial you are inspecting. You are welcome to inquire with the applicant, or with BRS, regarding the history of previous, similar notifications at the site to be inspected if you think that it may be relevant or helpful to your inspection.
- ◆ STATE(S). One notification may include approval for field trials in multiple states. You should proceed with an inspection only with a notification that is valid for your state.

Procedures

Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

- ◆ **LOCATION(S).** One notification may include approval for field trials in multiple locations within a state. If there are multiple field trial locations for this notification number within your state, coordinate with the BRS Regional Biotechnologist prior to inspection to determine which of these locations you will be inspecting.
- ◆ **SITE(S) AT LOCATION(S).** One notification may include approval for multiple field sites within a field trial location. For example, at one farm there may be seven fields on which the regulated article is grown. If there are multiple sites within one location, coordinate with the BRS Regional Biotechnologist prior to inspection to determine which of the sites you will be inspecting.

C. Inspector name & title —Record the name of the lead inspector for this inspection.

D. Inspector phone —Record the office and mobile telephone numbers of the lead inspector for this inspection.

E. Inspector location —Record the location where correspondence from USDA should be directed to the lead inspector for this inspection.

F. Notification Holder —Record the name of the notification applicant as it is listed on the notification record.

G. Cooperator at site —Record the name of the responsible party at the site during the time of the inspection. Record the names, affiliations and contact information of other persons present during the inspection.

H. Cooperator phone —Record the telephone number(s) of the responsible party at the inspection. If possible, record the office number and the mobile number of the responsible party.

I. Name(s) of staff in planting —Record the names and titles of all other persons present at the inspection, including organization staff, state agency representatives, and other USDA personnel.

J. General location —Record the general location information for the field trial location (such as farm mailing address, county and state) that is listed in the notification. If there are multiple locations, list these in the narrative section of your report.

K. Field trial site GPS coordinates —Record the global positioning system (GPS) coordinates taken at the field trial sites viewed at this inspection. Provide coordinates in degree decimal minute format (N00°

00.0000', W00° 00.0000). Only one GPS coordinate per field trial site is necessary; report on the location at which the coordinate is measured (i.e. NW corner).

L. Inspection date —Record the date(s) of the notification inspection. Specify dates for each of the different locations or sites visited.

M. Inspection start time —Record the time(s) at which the inspection occurred.

Procedural Requirements Section of Notification Inspection Worksheet

In the following section, each of the questions posed in the Notification Inspection Worksheet are systematically addressed.

The Notification Inspection Worksheet has been designed to follow the current regulatory requirements for genetically engineered organisms that are grown as experimental field trials in the U.S. under the Notification process. Each section of the questions is directly relevant to a section of the federal regulations that the applicant must meet in order to have a Notification acknowledged, valid, and in compliance.



Important

7 CRF 340.3(d) Procedural requirements for notifications

340.3(d) (6) Access shall be allowed for APHIS and State regulatory officials to inspect facilities and/or the field trial site and any records necessary to evaluate compliance with the provisions of paragraphs (b) and (c) of this section.

No.	Question	Yes	No	N/A
1.	Does the notification you receive from BRS exactly match the one held by the responsible party on site?			

This question addresses the responsibility of the notification holder to provide the inspector and BRS with a valid, up-to-date notification for use in the inspection.

The responsible party is required to have a copy of the valid notification on site, and available for review by the inspector.

Ask the responsible party to explain any discrepancies between the notification you received from the BRS Regional Coordinator and the one that is being used on site.

Procedures

Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

Ask the responsible party to explain if there are any revisions that have been made to the notification file used on site, including:

- ◆ Revised maps of the site(s) in the field trial that reflect planting or management plans
- ◆ Approved amendments to the original notification
- ◆ Additional performance standards
- ◆ Supplemental notification conditions

Look for any discrepancies between the notification filed at BRS and the one being utilized by the responsible party.

Note changes to field maps, procedures, and management plans. Obtain and forward copies of revised records, such as maps, with your report.



7 CFR 340.3(c) Performance standards for notifications

7 CFR 340.3(c) (1) If the plants or plant materials are shipped, they must be shipped in such a way that the viable plant material is unlikely to be disseminated while in transit and must be maintained at the destination facility in such a way that there is no release into the environment.

No.	Question	Yes	No	N/A
2.	Do the shipping and packing containers used for this field trial meet the performance standards			

This question addresses the movement of seed, plant tissue or other regulated article as it is being transported by shipping service or vehicle to and from the field trial site(s).

Ask the responsible party to show (if present) or describe (if absent) any packaging and containers used to ship or haul the regulated article to and from the site(s). Examine any containers described in the notification that are on site.

Look for any signs of poor container quality or container failure, such as bins with cracks, and bags or boxes that are torn.

Note and describe in your report narrative any deficiencies in packaging or transport containers observed, as well as a lack of ability on the part of the responsible party to adequately explain what containers were used if containers are absent.

The "Not Applicable" (NA) box should be checked if the inspection occurs mid-season, unless the responsible party has a detailed recollection of these items.

No.	Question	Yes	No	N/A
3.	Were packing and shipping materials used for this field trial cleaned out and disposed of to meet performance standards?			

This question addresses the movement of seed, plant tissue or other regulated article as it is being transported by shipping service or vehicle to the field trial site(s).

Ask the responsible party to show (if present) or describe to you (if absent) how packaging and containers were cleaned or disposed of after use.

Note and describe in your report narrative any deficiencies in the cleaning and destruction of packaging or transport containers present, as well as a lack of ability on the part of the responsible party to adequately explain what happened to these materials after regulated articles were removed (when absent).

The "Not Applicable" box should be checked if the inspection occurs mid-season, unless the responsible party has a detailed recollection of these items.

No.	Question	Yes	No	N/A
4.	Were transport or storage containers employed so as to fully contain the regulated article at the field trial location?			

This question addresses how the regulated article is contained while it is being stored and transported at the field trial location(s).

Ask the responsible party to show (when present) or describe to you (when absent) containers used to store the regulated article inside or outside of facilities, used to move the regulated article to and from storage to the planting site, and used for containment at harvest.

Ask the responsible party to tell you about any failures to fully contain the regulated article during transport, planting, and harvesting. Federal regulations require that APHIS BRS be notified in 24 hours in the event of an inadvertent introduction of the regulated article outside of approved containment structures, or outside of the field trial site.

Procedures

Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

If present, look for any signs of poor container quality or container failure, such as bins with cracks, bags or boxes that are eaten through by animals, containers that are outside but not secured, or trucks and combines that have bins that are not well sealed or cleaned.

Note and describe in your report narrative any deficiencies in storage or transport containers present, as well as a lack of ability on the part of the responsible party to adequately describe the containers used (when absent).



340.3(c) Performance standards for notifications

340.3(c) (2) When the introduction is an environmental release, the regulated article must be planted in such a way that they are not inadvertently mixed with unregulated plant materials of any species which are not part of the environmental release.

No.	Question	Yes	No	N/A
5.	Do descriptions or records demonstrate that equipment used in this field trial was cleaned so as to meet performance standards?			

This question addresses equipment cleaning procedures employed so as to prevent the inadvertent mixture of the regulated article with unregulated articles through the field trial season.

Notification inspections often occur regardless of the timing of field operations. Therefore, under most circumstances, you will not be present to observe how equipment is used and cleaned during field trial operations. The responsible party is expected to have a record or detailed recollection of equipment cleaning operations.

Ask about information from the records in the responsible party's possession, or obtain detailed verbal descriptions from the responsible party on:

- ◆ What equipment was used and cleaned?
- ◆ What procedures were used in cleaning equipment?
- ◆ Where did the equipment cleaning take place?
- ◆ Was the equipment subsequently used for unregulated food or feed crops?

Look at documents or ask for details about equipment cleaning processes, and for signs of competence and experience in equipment cleaning on the part of staff regarding equipment clean out procedures and related processes.

If no records have been kept for procedures that are designed to prevent commingling of the regulated article during cleaning of equipment, or if the responsible party fails to recall such information in sufficient detail, these incidents should be noted in your report as a potential deviation from federal regulation.



7 CFR 340.3(c) Performance standards for notifications

7 CFR 340.3(c)(3) The plants and plant parts must be maintained in such a way that the identity of all material is known while it is in use, and the plant parts must be contained or devitalized when no longer in use.

No.	Question	Yes	No	N/A
6.	Did the responsible party maintain identity of the regulated article at all times during handling and growing (seed storage, planting/harvest, etc.)?			

This question addresses the ability of the regulator and the responsible party to identify and keep segregated seed or plant tissue of the regulated article at all stages of the field trial.

The inspector is looking for evidence of a clear, effective identification system whereby the permit holder and responsible party on site can reliably locate, identify, differentiate and segregate the regulated article(s) at all field trial sites throughout the field trial process. It is particularly important that the article be identified so that mixture with other unregulated materials that may be stored or growing nearby is prevented.

Look for ways in which the regulated article is identified at different stages of the field trials, such as during shipping, while stored in containers, and when planted in the field trial site.

Questions to consider during the inspection include:

- ◆ Are identification materials in use durable enough to persist through the field season, including environmental conditions and field operations?
- ◆ Can the responsible party, and any field workers employed on the site, identify the regulated article using the system that is present?

Procedures

Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

- ◆ Are there redundancies in identification systems used?
- ◆ Can the boundary of the field site be identified even if the site is mowed or blown down?
- ◆ Can the field site be identified by the responsible party if the field map being used is lost?
- ◆ Can the field site be identified following the trial to mark the plot for volunteer monitoring?

Note and describe in your report narrative any deficiencies in identification methods or equipment used for the regulated article at all growth stages, as well as a lack of ability on the part of the responsible party to adequately explain the identification system.

Note and describe any inability or confusion on the part of the responsible party to explain the location and identification of all regulated articles growing on the site for this notification.

No.	Question	Yes	No	N/A
7.	Are there written records or descriptions showing that equipment and cleaning areas used in this field trial are, or will be, treated so as to devitalize the regulated article?			

This question addresses the regulatory requirement to assure containment of the regulated article during the field trial. The responsible party employs staging areas for the loading and unloading of equipment (such as planters, combines and mowers) and thorough cleaning of equipment at the field trial site in order to achieve this performance standard.

Staging areas are often located within the field trial site borders to keep articles within the site during these processes. There may be additional staging areas in storage barns or sheds.

After equipment is cleaned, the full and effective confinement and devitalization of the regulated propagative material removed from equipment is required. Devitalization procedures are intended to destroy viable plant material (such as tubers, seeds or rhizomes), and may include milling, incineration, or heat treatments.

Equipment that is used in the cleaning and devitalization process, such as vacuums, hoses, hoes, rakes, and mills should also be cleaned to assure complete confinement.

Effective containment in the cleaning and devitalization processes requires that the responsible party maintain and employ the highest standards of quality management in their operations.

Questions to consider include:

- ◆ How is seed or tissue removed from the equipment subsequently devitalized and disposed of?
- ◆ Does the responsible party clean the site(s) used for cleaning and devitalization of seed or tissue from equipment?
- ◆ Can the responsible party provide you with verbal or written details about the cleaning of equipment so as to devitalize the regulated article?

Ask the responsible party to tell you about any failures to fully contain and devitalize the regulated article after equipment clean out. Federal regulations require that APHIS BRS be notified immediately and in writing within 24 hours in the event that containment of the regulated article has been compromised.

Look at drainages or ditches in staging areas to determine if the regulated article is prevented from entering drains or ditches.

Note and describe in your report narrative any deficiencies in devitalization procedures and processes. Describe any inability or confusion on the part of the responsible party to explain their devitalization procedure and processes.



7 CFR 340.3(c) Performance standards for introduction under the notification procedure.

7 CFR 340.3(c)(5) The field trial must be conducted such that: (i) The regulated article will not persist in the environment, and (ii) No offspring can be produced that could persist in the environment.

No.	Question	Yes	No	N/A
8.	Did the notification holder or cooperator provide you with an up-to-date map of sufficient detail showing the field site(s) for regulated articles under this notification?			

This question addresses the requirement that the responsible party maintains and provides accurate information regarding the location of the regulated article at all times.

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Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

The applicant is required to provide you with an accurate, up-to-date map of the field trial sites at the location you are to visit either before or on the inspection date. If a map is not provided by the responsible party, note this in your report and illustrate your own map during the inspection.

The map that you are provided should include information about:

- ◆ The position of the field site(s) that are at the location,
- ◆ Size, shape and marking of the field site(s)
- ◆ Location of border rows, if any
- ◆ Location of multiple regulated articles within site(s), if any
- ◆ Crop types and fields adjacent to the field site(s)
- ◆ Storage and staging areas for the regulated article at that location
- ◆ Structures and buildings, such as barns, commercial businesses, schools, churches, and irrigation systems
- ◆ Major nearby geographic features (such as waterways, waste areas, steep inclines or declines)
- ◆ GPS coordinate(s) for field trial site(s)
- ◆ Compass point

Relate the GPS coordinates you have taken in the field site(s) to corresponding field sites drawn on your map.

Look at major features in the field to confirm the map provided to you.

Note and describe any inability or confusion on the part of the responsible party to explain the presentation of information about the field trial site(s) on the map.

Note, describe and correct any inaccuracies in the map when compared to what you observe in the field.

Submit any new or corrected map with your report to USDA APHIS BRS.

No.	Question	Yes	No	N/A
9.	Is the total area of the field site(s) at or below the total amount of acreage approved in the notification record?			

This question addresses the requirement that the regulated article be planted at a known, approved and limited acreage.

One notification may include approval for multiple sites within one field trial location, but all sites have to have a total acreage no greater than what is listed in the notification record.

The notification record usually **does not** provide information about the number of field trial sites at a given location. Prior to undertaking the inspection, ask the responsible party about:

- ◆ How many sites are present at the location for that notification record?
- ◆ What is the proximity of one site to another, so that you can determine the time necessary to travel between each site?
- ◆ What is size of each site, so that you can prioritize which sites to visit based on acreage?
- ◆ What organisms are planted at each site in order to prioritize inspection based on number or type of organism?

If necessary, discuss with the BRS Regional Biotechnologist if all sites should be visited at that location, or only a subset.

Note any deviations from the notification record regarding location of sites and regulated article present at each site.

If any or all of sites appear to exceed the total area approved in the notification, measure the field site(s) to confirm the length and width of outer perimeter and calculate the area. The outer perimeter of the field trial is that which surrounds, and therefore includes, any fallow zones or border rows around the regulated article.

Note the size of all field sites inspected at the location in your report. (A location may include several sites.)

Note any acreage for the field trial that is above what is listed in the notification, and describe any individual field sites that may account for the overplanting observed.

No.	Question	Yes	No	N/A
10.	Are the type(s) of regulated article(s) in field trials at location (organism/trait) exactly and only those stated in the notification?			

This question addresses the requirement that the regulated article be planted in a way that prevents persistence and commingling with unregulated organisms.

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Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

Notifications may include approval for multiple regulated articles within one field site, or several different notifications may be planted very near one another. In either instance, carefully review the notification to ascertain the following:

- ◆ What regulated article(s) are listed in the notification you are reviewing,
- ◆ The rules regarding the proximity of a field trial to any related species.

After reviewing the notification, verify that the site you are inspecting meets the requirements for what should be planted at that location, according to the notification you have in hand. Note in your report the presence of other field trial sites in a close proximity to the one that you are inspecting.

Changes to the types of organisms grown in the field trial site have to be approved by BRS, and approvals for those changes have to be part of the notification record. Notifications cannot be amended by the applicant without BRS approval.

Note any deviations from the notification regarding the species or traits planted on the site.

No.	Question	Yes	No	N/A
11.	If border rows are present in the field trial site, are they grown so as to meet performance standards?			

This question addresses the requirement that the regulated article be planted in a way that prevents persistence and commingling with unregulated organisms.

Because border rows are often the same crop type as the regulated article, they must be carefully managed to maintain segregation during the field trial.

Border rows are regulated articles, and must be treated as such throughout and after the field trial. Inadvertent harvesting or commingling of the border row with unregulated material is a deviation from federal regulation.

The type of crop and total land area used in border rows should be accounted for in the notification records or map.

Border row area may have been used as a staging area in the early season of the field trial, so that seed spillage may have occurred in this area.

Ask the responsible party how the border rows will be devitalized at the end of the field trial.

Ask if the border row has been sampled or used as an unregulated article (*i.e.* for food, feed, or propagation purposes) outside of the field trial area.

Look at the field site to determine if border rows are effectively distinguished from unregulated articles.

Note if the responsible party has used or perceived the border row as an unregulated article.

Note if the responsible party cannot distinguish the border rows from unregulated articles in fields adjacent to the field trial.

The “Not Applicable” (NA) box should be checked if border rows are not used in this field trial.

No.	Question	Yes	No	N/A
12.	Are measures being employed as to minimize or prevent expected human or animal incursion onto the field trial?			

This question addresses the requirement that the regulated article be planted in a way that prevents persistence and commingling with unregulated organisms.

It is not a federal requirement that sites be maintained in a specific way to prevent human or animal incursion if such is not anticipated during the course of the field trial.

In most instances, the remoteness of most sites is the primary control for human incursion employed by the notification holder. Some sites, however, are in locations with a considerable amount of human and animal activity, such as experimental research centers in urban environments or fields adjacent to wildlife habitats; these are the locations at which you should note a failure to control for expected human or animal incursion onto the field trial site.

Ask the responsible party if animal or human incursion on the site has happened, or is expected.

If human incursion is expected, look at the field site to determine what measures have been taken to minimize the event, such as a durable sign, screen or fence.

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Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

Note any present or potential future difficulty that members of the public may experience in observing and honoring the boundary of the field trial in areas frequented by the public, seasonal workers, or other groups.

If wildlife or livestock incursion is expected, look at the field site to determine if any techniques are being employed to prevent or discourage animal incursion onto the site.

Note the nature and extent of expected animal incursion on the site, and the extent and quality of animal exclusion methods employed.

The “Not Applicable” box should be checked if no animal or human incursion is expected.

No.	Question	Yes	No	N/A
13.	If flower removal was used to control reproduction, was it employed successfully?			

These questions address the requirement that the regulated article be planted in a way that prevents persistence and cross-pollination of the regulated article with unregulated organisms.

Flower removal is an option for control of reproduction in only a few crops, primarily corn.

Effective flower removal requires that flowers are removed at the appropriate time to prevent undesired cross-pollination.

During the growing season, look at the regulated article to determine if flower removal was complete if flower removal has occurred.

Before or after the growing season, examine documents that describe what procedures are used for flower removal, and review records or obtain a verbal description of when and how flower removal occurred.

Ask if staff that participated in the flower removal were trained in flower removal and proper procedures for working with regulated articles. You can request more information about training programs utilized for this effort.

Note any failure to fully remove flowers from the regulated article using correct methods, at the correct time, or in a complete way.

Note if any staff were used in the field trial for deflowering who were not trained on procedures related to the management of regulated articles.

The “Not Applicable” (NA) box should be checked if flower removal is not used in this field trial.

No.	Question	Yes	No	N/A
14.	If flower bagging was used to control reproduction, was it employed successfully?			

These questions address the requirement that the regulated article be planted in a way that prevents persistence and cross-pollination of the regulated article with unregulated organisms.

The bagging of flowers is an option for control of reproduction in many crops.

Effective bagging requires that bags are placed at the appropriate time and using proven methods to prevent undesired cross-pollination.

During the growing season, look at the regulated article to determine if bagging was complete if flowering has occurred.

Before or after the growing season, examine records that describe 1) procedures used in bagging and 2) dates on which bagging occurred. If records were not kept, ask for and note a detailed description of both the procedure and dates on which the bagging was done.

Questions you might ask include:

Does the responsible party have appropriate material to bag reproductive structures?

Were all flowers bagged?

Did/will the responsible party provide written records or detailed recollection of when, and how, the bags were placed and/or removed?

Ask if staff that participated in the bagging were trained in proper procedures for working with regulated articles. You can request more information about training programs utilized for this effort.

Note any failure to fully bag flowers from the regulated article using correct methods, at the correct time, or in a complete way.

Note if any staff were used in the field trial for bagging who were not trained on procedures related to the management of regulated articles.

The “Not Applicable” (NA) box should be checked if flower bagging is not used in this field trial.

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Guidance for Completing the Notification Inspection Worksheet and Summary of Findings

No.	Question	Yes	No	N/A
15.	If border rows were used to control reproduction, were they employed successfully?			

These questions address the requirement that the regulated article be planted in a way that prevents persistence and cross-pollination of the regulated article with unregulated organisms.

The use of border rows is an option for control of reproduction in some crops.

Note any failure to plant borders as stated in the notification, and observations of growth habit or maintenance on the border that may decrease its efficacy as a barrier to pollination.

The “Not Applicable” (NA) box should be checked if border rows are not used in this field trial.

No.	Question	Yes	No	N/A
16.	If temporal isolation (flowering time) was used to control reproduction, was it employed successfully?			

This question addresses the requirement that the regulated article be planted in a way that prevents persistence and cross-pollination of the regulated article with unregulated organisms.

The use of temporal isolation is an option for control of reproduction in some crops.

Questions you might ask include:

Was the regulated article planted early enough to avoid any possible cross pollination with sexually compatible plants inside the isolation distance for this crop?

When was the regulated article planted? When did or will the regulated article flower?

What was the date when the sexually compatible species planted?
When did or will the compatible species flower?

When did you monitor to observe flowering in the regulated article and compatible species?

Note any failure to plant the regulated article so as to achieve flowering at a time that is out of synchrony with flowering of any nearby, related crops or plants.

Note any failure to keep records on the timing of planting and flowering of the regulated article.

The “Not Applicable” box should be checked if temporal isolation is not used in this field trial.

No.	Question	Yes	No	N/A
17.	Is the area within the isolation distance for the regulated article field trial site(s) free of sexually compatible plant species ?			

This question addresses the requirement that cultivated crops, wild, weedy or volunteer plants that are sexually compatible with the regulated article be controlled in a way that prevents persistence and cross pollination with the regulated article.

Cultivated crops related to the regulated article that are found within the area bounded by the isolation distance for the article must be controlled so that there is no opportunity for cross pollination and seed set in these related plants.

Questions you might ask include:

Are any **cultivated plantings** of related plant species located inside the isolation distance for the regulated article at the field trial site(s)?

Are all **wild, weedy or volunteer plants** related to the regulated article located inside the isolation distance for the regulated article at the field trial site(s)?

Does the responsible party have records or a detailed recollection of the dates on which **sexually compatible plants**, if any, were removed from within the isolation area of the field trial? What methods were used to remove them?

Look in fields that fall within the isolation distance for the regulated article to determine if sexually compatible plants are present.

Note the occurrence of any sexually compatible plants within the isolation distance for the crop. Determine if the period of flowering for the related species will coincide with the period of flowering for the regulated article.

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Look at records of chemical and cultural control methods used to eradicate related plants within the isolation distance of the regulated article.

Note the failure to record or employ the application of treatments to eradicate related plants in the field trial site, and surrounding isolation distance area. (See **Figure 3-1, “: Crops that have free living populations of the same species or sexually compatible free living relatives,”** on page-3-44).



7 CFR 340.3(c) Performance standards for introduction under the notification procedure.

7 CFR 340.3(c)(6) Upon termination of the field test:

- (i) No viable material shall remain which is likely to volunteer in subsequent seasons, or
- (ii) Volunteers shall be managed to prevent persistence in the environment.

No.	Question	Yes	No	N/A
18.	Does the notification holder have a description or records for monitoring volunteers for these field trial site(s) next year?			

This question addresses the requirement that plants related to the regulated article be controlled in a way that prevents persistence of the regulated article at the field trial site(s).

Plants related to the regulated article that are found within the field trial area in subsequent year(s) must be controlled so that there is no opportunity for cross pollination and seed set in related plants.

If monitoring **has begun**, look at records or get a description of monitoring undertaken to located sexually compatible plants within the field trial site during the growing season.

If monitoring **has not begun**, as about future monitoring schedules and plans, and determine if the responsible party has planned sufficiently to identify and control volunteers.

Note the failure to plan for, record or undertake scouting for volunteers in the field trial site. Please note any volunteers present during the inspection.

**7 CFR 340.3(d) Procedural requirements for notifying APHIS.**

7 CFR 340.3(d)(4) Field test reports must be submitted to APHIS within 6 months after termination of the field test. Field test reports shall include the APHIS reference number, methods of observation, resulting data, and analysis regarding all deleterious effects on plants, nontarget organisms, or the environment.

No.	Question	Yes	No	N/A
19.	Do descriptions or records demonstrate that the responsible party is monitoring for any deleterious effects by regulated article on itself, other plants, nontarget organisms, or the environment?			

This question addresses the monitoring of the regulated article for any deleterious effects that it may have as observed during the field trial. Deleterious effects are those that are harmful in a subtle or unexpected way.

The responsible party is expected to monitor the regulated article during the field trial to observe for, and report on, any harmful effects observed. The responsible party is expected to observe for any unexpected vulnerability to pests, unusual growth characteristics, or other perceived problems in the regulated article itself. The responsible party is also observing for any pest-like characteristics expressed by the regulated article, such as weediness, as well as harm to nontarget insects or wildlife.

Ask the responsible party about the methods that are being used to make observations of deleterious effects.

Ask the responsible party which deleterious effects are being monitored for.

Questions you might ask include:

- ◆ Are you observing for effects of the regulated article on nontarget organisms or other plants?
- ◆ Are you looking for other environmental effects of the regulated article?
- ◆ How are you making those observations?
- ◆ Who is making these observations, and how were they trained?
- ◆ How frequently are you making those observations?

- ◆ What is your method of recording and reporting deleterious effects?

Look at any field notebook records used by the responsible party in monitoring for deleterious effects, if such is being used.

Describe in your narrative report the methods used for making observations and reporting deleterious effects as described by the responsible party. Note any deficiencies in the methods used to undertake observations about deleterious effects.

Guidance to Performance Standards

The performance standards are a set of six conditions that must be met in order to assure containment of the field trial of transgenic plants. The goal of the performance standards is to manage the field trials of the transgenic plant so that its offspring will not persist in the environment. To give applicants flexibility in managing their field trials, the performance standards may be met by various protocols.



This variability is why it will be necessary for the inspector to request a copy of each applicant's protocols before the inspection.

In this section, we will review the following six performance standards described in 7 CFR 340.3(c):

1. Shipping and maintenance at destination (7CFR 340.3(c)(1))
2. Inadvertent mixing of materials in environmental releases 7CFR 340.3(c)(2))
3. Identify and devitalization (7CFR 340.3(c)(3))
4. Viable vector agents (7CFR 340.3(c)(4))
5. Persistence in the environment (7CFR 340.3(c)(5))
6. Volunteer plants 7CFR 340.3(c)(6))

Most performance standards can be grouped into the following three areas for inspection:

- ◆ Shipping, maintenance at destination, and inspection
 - ❖ Shipping and maintenance at destination (Performance standard 1)

- ◆ Field trial site requirements addressing inadvertent mixing, persistence, and volunteer plants
 - ❖ Inadvertent mixing of materials in environmental releases (Performance standard 2)
 - ❖ Persistence in the environment (Performance standard 5)
 - ❖ Volunteer plants (Performance standard 6)
- ◆ Devitalization
 - ❖ Identify and devitalization (Performance standard 3)

Performance Standard 4 (viable vector agents) is primarily a concern for interstate movement and importation of newly transformed plant material, and does not require inspection in the field.

Shipping, Maintenance at Destination, and Identification

Control and containment of the regulated article has to happen through every stage of the field trial planning and production process. In order to achieve complete containment of plant materials, containers, vehicles and buildings used for the movement of the regulated plant material must be inspected for their quality and durability. The identification system used to track the regulated plant material must be clear and visible throughout the movement process.

For regulated plant material, the shipping container must consist of an inner container that is a sturdy bag, box, or other such structure. Both inner container and outer container must be capable of preventing seed or material loss. Small seeds like tobacco could be treated similarly, but the inner container should be a sealed bag; lidded bottle, jar, metal can; or other appropriate container sufficient to contain small size seeds.

The identity requirements for regulated material extends over all aspects of the field trial. Unidentified seed or other plant material should not be present at any phase.

To prevent inadvertent mixing of regulated and unregulated material, a uniform identification system should be implemented, such as obvious markers and labeling systems, obvious morphological differences, color-coding, and strict segregation.

Field Trial Requirements Addressing Inadvertent Mixing, Persistence, Related Plants, and Volunteers

This is the most technical, difficult, and variable standard because it deals with the biology of the plant and field site location. One of the most critical performance standards is to ensure that the transgenic plants do not pollinate sexually compatible plants that are nearby, including other cultivated plants or free-living plants of the same crop species, and any compatible wild plants of a species related to the crop. Free-living plants refers to plants that grow outside of cultivation or where they have not been planted. Sexually-compatible means that the cultivated plant can cross-pollinate with each other successfully. The applicant should know whether or not the crop plant has compatible free-living or wild relatives near the field trial site. **See Table 3-1, “: Crops that have free living populations of the same species or sexually compatible free living relatives.” on page 44** for a listing of common crops that have free-living relatives in the United States; this list is not complete. If questions arise on crops with unknown free-living relatives, the inspecting officer should immediately contact the regional biotechnologist for advice and, if necessary, a staff biotechnologist can advise you.

TABLE 3-1: Crops that have free living populations of the same species or sexually compatible free living relatives.

Crop Compatible:	Free Living Species:
Alfalfa (<i>Medicago sativa</i>)	Same species
Asparagus (<i>Asparagus officinalis</i>)	Same species
Beet (<i>Beta vulgaris</i>)	Sea beet (not found near most production areas in the Central Valley of CA)
Bermuda grass (<i>Cynodon dactylon</i>)	Same species
Blackberry (<i>Rubus</i> spp.)	Same species
Blueberry (<i>Vaccinium angustifolium</i>) and <i>V. corymbosum</i>	Same species and other <i>Vaccinium</i> spp.
Canola (<i>Brassica napus</i>)	Same species and <i>B. campestris</i> , <i>B. juncea</i>
<i>Chenopodium quinoa</i> (a grain)	<i>C. berlandieri</i>
Carrot (<i>Daucus carota</i>)	Same species
Celery (<i>Apium graveolens</i>)	Same species
Chickory (<i>Chicorium intybus</i>)	Same species
Clover (<i>Trifolium</i> spp.)	Same species

TABLE 3-1: Crops that have free living populations of the same species or sexually compatible free living relatives. (continued)

Crop Compatible:	Free Living Species:
Cranberry (<i>Vaccinium macrocarpon</i>)	Same species
Grape (<i>Vitus vinifera</i>)	Wild grape (<i>Vitus</i> spp.)
Lettuce (<i>Lactuca sativa</i>)	Wild lettuce (<i>L. serriola</i>)
Oat (<i>Avena sativa</i>)	Wild oats (<i>A. fatua</i>)
Oilseed rape (<i>Brassica napus</i>)	Same species and <i>B. Camprestris</i> , <i>B. juncea</i>
<i>Populus alba</i> x <i>P. grandidentata</i>	Many populus species
Radish (<i>Raphanus sativus</i>)	Same species, <i>R. raphanistrum</i>
Raspberry (<i>Rubus</i> spp.)	Same species
Rice (<i>Oryza sativa</i>)	Same species = <i>O. sativa</i> var. <i>Spontanea</i> , red rice
Serviceberry (<i>Amelanchier laevis</i>)	Same species
Sorghum	Johnsongrass (<i>S. halapense</i>)
Spruce (<i>Picea glauca</i>)	Same species
Squash (<i>Cucurbita pepo</i>)	Same species = <i>C. texana</i>
Strawberry (<i>Fragaria</i> sp.)	<i>F. virginiana</i> , <i>F. chiloensis</i> , <i>F. vesca</i> , and <i>F. ovalis</i>
Sunflower (<i>Helianthus annuus</i>)	Same species
Sweetgum (<i>Liquidambar styraciflua</i>)	Same species
Tobacco (<i>Nicotiana tabacum</i>)	Same species
Turnip (<i>Brassica rapa</i>)	Same species = <i>B. campestris</i>
Walnut (<i>Juglans regia</i>)	<i>J. hindsii</i>
Wheat (<i>Triticum aestivum</i>)	Jointed goatgrass (<i>Aegilops cylindrica</i>)

In order to prevent offspring from being formed and persisting, procedures must be taken to minimize the likelihood of pollination and successful fertilization of receptive plants outside the field trial. These procedures will vary with the biology of the plant. Five of the most common procedures sometimes used in combination are the following:

- ◆ Removing flowers
- ◆ Bagging of flowers/tassels to prevent open pollination
- ◆ Terminating the experiment prior to flowering
- ◆ Physical isolation
- ◆ Temporal isolation of pollination

Removing flowers

Flower removal is usually employed on smaller plots, where the labor necessary to pull flower parts over time can realistically be achieved. In corn, larger detasseling efforts have been undertaken in breeding programs for many years, so that flower parts can be successfully removed over much larger acreages. Flower removal methods tend to fail in the following circumstances:

- ◆ When they are applied only during a short period for a crop that has a long flowering period
- ◆ When applied in crops that produce secondary flowers from stems or tillers
- ◆ When undertaken by staff that are not well trained on flower removal techniques for a particular crop

Bagging of flowers/tassels to prevent open pollination.

The placement of bags over flowers is usually employed on smaller plots, where the labor necessary to place bags in a timely manner can be realistically achieved. Bagging of flowers is often used in breeding programs for cereal grains and legumes, as well as a wide array of horticultural crops. Bagging methods tend to fail when they come off in windy weather, disintegrate in the field over the season, or are applied for a short period for a crop that has a long flowering period.

Terminating the experiment prior to flowering.

Termination of the plant represents a method of reproductive control for field trials in which the regulated plant is terminated prior to flowering. Plant varieties have varying maturity times and plant development may vary due to environmental factors.

Physical isolation

The physical isolation distance for foundation seed has been approved by USDA as a means to minimize cross-pollination of the regulated plant with non regulated relatives. This prevents the development of persistent offspring outside the field trial. The use of physical barriers, such as cages, may also be a method by which cross-pollination is prevented (particularly when a crop is insect pollinated). As an option, applicants may surround the test plot with border rows in addition to the measures above to trap the pollen or to physically prevent it from leaving the test plot.

Check the notification or permit to determine what physical isolation methods have been approved to prevent fertilization, seed production and environmental persistence. (The certified foundation seed distances for most crops can be found in **Table 3-2, “: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76,” on page-3-47** or at our Web site at: [http:// www.aphis.usda.gov/brs/isolate.html](http://www.aphis.usda.gov/brs/isolate.html).)

TABLE 3-2: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76

Crop Kind:	Foundation Distance:
Alfalfa (Non hybrid)	<p>600 feet</p> <ul style="list-style-type: none"> ◆ Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields ◆ This distance applies for fields over 5 acres. For alfalfa fields of 5 acres or less that produce the Foundation and Registered seed classes, the minimum distance from a different variety of a field of the same variety that does not meet the varietal purity requirements for certification shall be 900 and 450 feet, respectively.
Alfalfa (Hybrid)	<p>1320 feet</p> <ul style="list-style-type: none"> ◆ Parent lines (A and B) in a crossing block or seed and pollen lines in a hybrid seed production field shall be separated by at least 6 feet and shall be managed and harvested in a manner to prevent mixing.
Barley (Non hybrid)	<p>0 feet</p> <ul style="list-style-type: none"> ◆ Distance adequate to prevent mechanical mixture is necessary. For non hybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.
Barley (Hybrid)	<p>660 feet</p> <ul style="list-style-type: none"> ◆ Isolation distances between two fields of the same kind may be reduced to a distance adequate to prevent adequate mechanical mixture if the sum of percentages of plants in bloom in both fields does not exceed 5 percent at a time when more than 1 percent of the plants in either field are in bloom. ◆ An unplanted strip at least 2 feet wide shall separate male sterile plants and pollinator plants in inter-planted blocks
Beans (Field and garden, Mung, Broadbean)	<p>0 feet</p> <p>Distance adequate to prevent mechanical mixture is necessary. For non hybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.</p>
Clover (all kinds)	<p>600 feet</p> <ul style="list-style-type: none"> ◆ Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields ◆ This distance applies when fields are 5 acres or larger in area. For smaller fields, the distances are 900 feet and 450 feet for the Foundation and Registered classes, respectively.

TABLE 3-2: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76 (continued)

Crop Kind:	Foundation Distance:
Corn	<p>660 feet</p> <ul style="list-style-type: none"> ◆ If transgenic corn is pharmaceutically modified, the physical isolation distance should be one mile for open-pollination. If pharmaceutical fields are close pollinated (de-tasseled or bagged tassels), the isolation distance is one half mile with temporal isolation of 28 days to non-permit corn. Additional information may be obtained by referring to protocols of a given permit, consulting the RBT, or a BRS biotechnologist. ◆ No isolation is required for the production of hand pollinated seed.
Cotton	<p>0 feet</p> <p>APHIS APPROVED ALTERNATIVE — A 40 foot-wide perimeter of non-transgenic cotton could surround the transgenic plants to act as pollen sink for insect pollinators. The perimeter cotton would be disposed of by harvesting, disking, and monitoring.</p> <ul style="list-style-type: none"> ◆ Minimum isolation shall be at least 100 feet if the cotton plants in the contaminating source differ by easily observable morphological characteristics from the field to be inspected. Isolation distance differ by easily observable morphological characteristics from the field to be inspected. Isolation distance between upland and Egyptian types shall be at least 1320 and 660 feet for Foundation, Registered, and Certified classes respectively.
Cowpea	<p>0 feet</p> <ul style="list-style-type: none"> ◆ Distance adequate to prevent mechanical mixture is necessary. For non hybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.
Crambe	660 feet
Crownvetch	<p>600 feet</p> <ul style="list-style-type: none"> ◆ Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields ◆ This distance applies when fields are 5 acres or larger in area. For smaller fields, the distances are 900 feet and 450 feet for the Foundation and Registered classes, respectively.

TABLE 3-2: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76 (continued)

Crop Kind:	Foundation Distance:
Cucurbits	No foundation seed distance reported (squash, melons) APHIS APPROVED ALTERNATIVE — A minimum of a 30 foot border row of the same non-transgenic species could surround the transgenic plants. Border row plants are treated as transgenic plants and are disposed in the same manner as transgenic cucurbits.
Flatpea	600 feet ◆ Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields ◆ This distance applies when fields are 5 acres or larger in area. For smaller fields, the distances are 900 feet and 450 feet for the Foundation and Registered classes, respectively.
Flax	0 feet
Grasses Cross-pollinated	900 feet ◆ Isolation between classes of the same variety may be reduced to 25 percent of the distance otherwise required. ◆ These distances apply when there is no border removal. Border removal applies only to fields of 5 acres or more. Removal of a 9-foot border (after flowering) decreases the required distance for Foundation, Registered, and Certified seed to 600, 225, and 100 feet respectively, for cross-pollinating species, and to 30, 15, and 5 feet, respectively for apomictic and self-pollinated species. Removal of a 15 foot border (after flowering) allows a further decrease to 450, 150, and 75 feet, respectively for cross-pollinated species.
Lespedeza	10 feet ◆ Isolation between classes of the same variety may be reduced to 25 percent of the distance otherwise required.
Millet ◆ Cross-pollinated	1320 feet ◆ Isolation between millets of different genera shall be 6 feet
Millet ◆ Self-pollinated	0 feet ◆ Distance adequate to prevent mechanical mixture is necessary.
Mustard	1320 feet

TABLE 3-2: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76 (continued)

Crop Kind:	Foundation Distance:
Oat	0 feet ◆ Distance adequate to prevent mechanical mixture is necessary. For non hybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.
Okra	1320 feet
Onion	5280 feet
Pea, field	0 feet ◆ Distance adequate to prevent mechanical mixture is necessary. For non hybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.
Peanut	0 feet ◆ Distance adequate to prevent mechanical mixture is necessary. For non hybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.
Pepper	200 feet
Potato (Male-sterile)	0 feet
Potato (Male-fertile)	30 feet
Rapeseed (Cross-pollinated)	1320 feet ◆ Required isolation between classes if the same variety is 10 feet.
Rapeseed (Self-pollinated)	660 feet ◆ Required isolation between classes if the same variety is 10 feet.
Rice	10 feet
Rye	660 feet
Safflower	1320 feet

TABLE 3-2: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76 (continued)

Crop Kind:	Foundation Distance:
Sainfoin	<p>600 feet</p> <ul style="list-style-type: none"> ◆ Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields ◆ This distance applies when fields are 5 acres or larger in area. For smaller fields, the distances are 900 feet and 450 feet for the Foundation and Registered classes, respectively.
Sorghum (Non hybrid)	990 feet
Sorghum (Hybrid Seedstock)	990 feet
Soybeans	<p>0 feet</p> <ul style="list-style-type: none"> ◆ Distance adequate to prevent mechanical mixture is necessary. For non hybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet.
Sunflowers (Non hybrid)	<p>2640 feet</p> <ul style="list-style-type: none"> ◆ Does not apply to <i>Helianthus similes</i>, <i>H. ludens</i>, or <i>H. Agrestis</i> ◆ An isolation distance of 5,280 feet is required between oil and non-oil sunflower types and between either type and other volunteers or wild types
Sunflowers (Hybrid)	<p>2640 feet</p> <ul style="list-style-type: none"> ◆ Does not apply to <i>Helianthus similes</i>, <i>H. ludens</i>, or <i>H. Agrestis</i> ◆ An isolation distance of 5,280 feet is required between oil and non-oil sunflower types and between either type and other volunteers or wild types
Tobacco (Non hybrid)	<p>150 feet</p> <ul style="list-style-type: none"> ◆ This distance is applied between varieties of the same type and may be waived if four border rows of each variety are allowed to bloom and set seed between the two varieties but are not harvested for seed. Isolation between varieties of different types shall be 1,320 feet except if protected by bagging or topping all plants in the contaminating sources before bloom.

TABLE 3-2: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76 (continued)

Crop Kind:	Foundation Distance:
Tobacco (Hybrid)	150 feet ◆ This distance is applied between varieties of the same type and may be waived if four border rows of each variety are allowed to bloom and set seed between the two varieties but are not harvested for seed. Isolation between varieties of different types shall be 1,320 feet except if protected by bagging or topping all plants in the contaminating sources before bloom.
Tomato	200 feet APHIS APPROVED ALTERNATIVE — Based on experimental results, common requirements would be isolation by at least 30 feet from other tomatoes to minimize pollen flow to any non-transgenic tomatoes.
Trefoil, birdsfoot	600 feet ◆ Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields ◆ This distance applies when fields are 5 acres or larger in area. For smaller fields, the distances are 900 feet and 450 feet for the Foundation and Registered classes, respectively.
Triticale	0 feet ◆ Distance adequate to prevent mechanical mixture is necessary. For nonhybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet
Vetch	10 feet
Vetch, milk	600 feet ◆ Distance between field of certified classes of the same variety may be reduced to 10 feet regardless of the class or size of the fields ◆ All cross-pollinating varieties must be 400 feet from any contaminating sources.
Watermelon	6240 feet APHIS APPROVED ALTERNATIVE — A minimum of a 30 foot border row of the same species. Border row plants are treated as transgenic and are disposed of in the same manner as transgenic watermelons. ◆ The minimum distance may be reduced by 50 percent if the field is adequately protected by natural or artificial barriers

TABLE 3-2: Isolation Distances in Feet From Any Contaminating Source Adapted from Table 5, 7 CFR Part 201.76 (continued)

Crop Kind:	Foundation Distance:
Wheat (Nonhybrid)	0 feet ◆ Distance adequate to prevent mechanical mixture is necessary. For nonhybrid wheat, the new required isolation distance (as of July 7, 2001) is 3 meters or 33 feet
Wheat (Hybrid)	660 feet

Table 3-2 does not include isolation distances for all crops under APHIS permit. Examples are: tropical fruit (papaya), sugar beets, trees (coffee, poplar, apple, and pear) and berries (blackberry, raspberry, and strawberry). Do not rely on this table solely to determine the approved physical isolation method for the field trial you will be inspecting. In permits under Form 2000, specified isolation distance and safeguards are written in the field plot design. Always check the notification or permit to determine the approved physical isolation method.

If questions arise on crops with unknown isolation distances, the inspecting officer should immediately contact the regional biotechnologist for advice and, if necessary, a staff biotechnologist can advise you.

Temporal isolation of pollination

This involves planting earlier or later than any sexually compatible plant within foundation seed certification distance. If this option is used, it will be necessary for the cooperator to monitor the test plot by walking the rows and inspecting the flowers to determine the onset of pollination. If it appears that the pollination period of the transgenic plants will overlap with that of nearby non-transgenic plants, then remedial methods must be taken. The time period from planting to flowering in many crops can vary depending on annual environmental conditions, which may negate the temporal isolation method in some years. Other conditions may prohibit the use of this method. Where appropriate, consult with a Regional Biotechnologist for guidance.

Growing site design and maintenance

For most material, inadvertent mixing of regulated material and non regulated material may be prevented by planting the regulated article in a defined area with an unplanted alley between it and any other material. The width of this alley will vary depending on the method of harvesting and other operations. For machine harvesting, the alley should be wide enough to allow for machine movement without mechanical mixing.

Volunteers

Volunteers shall be minimized by growing transgenic material in defined areas in the field and by performing adequate termination protocols. Applicants should have monitoring protocols of adequate duration to ensure that all volunteers have been eliminated by the methods described in the sections above. Volunteers can be eliminated by treating them with herbicides, plowing them under, or by roguing and collecting them by hand for devitalization.

The field site must be clearly identified because it needs to be separated from nearby non-transgenic plants. The site must remain identifiable the following growing season to ensure any volunteer transgenic plants that have grown are easily identified for later elimination. The use of Global Positioning Satellite (GPS) position locators are an excellent way to identify a site.

All machinery used for planting or harvesting that may retain reproductive parts must be cleaned after use in transgenic fields. If seeds or reproductive parts could be washed off of the equipment, the applicant should have a way of eliminating plants that might grow from these plant parts.

Devitalization

After the field trial is complete, seeds, ears, tubers, or other common reproductive materials are saved at the site or shipped to another contained facility. If there is plant material left over, including that sent to landfills, it must be non-reproductive or rendered non-viable. Non-viable plant material is not regulated under biotech regulations. Final disposition and devitalization is often achieved as follows:

- ◆ Transport to a laboratory for devitalization following harvest of all seeds, ears, tubers, or other common reproductive material.
- ◆ Remaining vegetative material (non-reproductive) in the field is incorporated into the soil and left to devitalization by the elements,
- ◆ Milled and deposited in a state licensed landfill. Depending on local conditions, some materials, such as potato tubers, may be devitalized by surface winter exposure in the field.

Contingency planning

Some applicants lack a useful contingency plan in case performance standards are not met. Therefore, remedial measures may not have been designed into the procedures. Please note on your report if a contingency plan exists.

Sample of Site Specific Protocols (for Notification)

On the following pages, are four examples of site specific protocols. These examples were approved by Biotechnology Permits and Risk Assessment Unit (BPRAU).

Permittees have flexibility in writing their protocols, but they must agree with scientifically acceptable practices for the given crop and must support the intent of the performance standards. Inspectors should carefully read the above guide for familiarity and understanding of the performance standards with special attention to “Procedures for Site Inspection (of Notification Sites).”

Performance standards must be written and submitted to the inspecting officer at the field site or faxed to the officer earlier, if convenient, if a site is to be inspected. This requirement is consistent for all notification field releases. The BPRAU will post this requirement on the internet and/or include it in the Acknowledgment of the permit letters to the permittee beginning in 2001.

If the permittee or cooperator does not have a copy of the site specific protocols at the time of inspection, it is a violation of permit. Also, it must be documented by date and included in the officer’s inspection report that is sent to the PPQ and BRS Regional Biotechnologists (RBTs).

The RBT will write a warning letter and place the concern on 2 years probation. A second violation in a 2 year period will result in a penalty.

Sample of Generic Protocols for Notification Field Release of Genetically Engineered Strawberry (*Fragaria x ananassa*)

Company X’s policy requires compliance with U.S. Department of Agriculture, Animal and Plant Health Inspection Service (USDA/ APHIS) regulations in 7 CFR 340 for the importation, movement, and

environmental release of all regulated plant materials. The principal investigator is responsible for complying with the following regulatory standards for field trials of genetically modified strawberries.

Shipping and Maintenance at Destination

- ◆ Regulated plant materials will be “double packaged” for shipping in containers which are independently capable of preventing loss of the plant materials.
- ◆ Shipping containers will be clearly labeled with the contents and the USDA permit or notification number.
- ◆ Regulated plant materials will be segregated from non-regulated materials during shipping and storage to prevent accidental mixing.

Inadvertent Mixing of Materials in Environmental Releases

- ◆ Regulated plant materials will be planted in a defined area the boundaries of which are identifiable by the principal investigator and other site personnel.
- ◆ Machinery used in the field trial will be brushed clean of fruit or seed within the area for transgenic planting before use in another area.

Identity and Devitalization

- ◆ Special colored markings will be placed in or on each container of regulated plant materials in a greenhouse.
- ◆ The boundaries of each field planting of regulated plant materials will be identifiable by the principal investigator and other site personnel until the end of the post-harvest monitoring period to aid in the detection of volunteers.
- ◆ Regulated plant materials from a greenhouse will be devitalized prior to disposal.
 - ❖ Pollen, fruit, and seed may be heated using dry heat or steam until nonviable then composted and discarded as trash
 - ❖ Leaves, stems, and roots may be composted or discarded as trash
- ◆ Regulated plant materials from a field trial may be diced into the soil for natural decay. The trial site will be monitored for the presence of volunteers as prescribed below.

Viable Vector Agents

- ◆ Regulated plant material will not be released into the environment until adequately treated to remove viable vector agents capable of transferring DNA.
- ◆ Regulated plant materials will be observed in the field for evidence of galls on roots, stems, and leaves that may indicate the presence of viable *Agrobacterium tumefaciens*. Observations will be recorded.
- ◆ Evidence of viable *A. tumefaciens* will require immediate removal of affected plants from the field.

Persistence in the Environment

- ◆ Regulated strawberry plants will be physically isolated from non-regulated commercial strawberry production by at least 100 feet.
- ◆ Regulated strawberry plants will be physically isolated from other strawberries being grown for seed or known stands of sexually compatible wild relatives by at least 3 miles.
- ◆ Regulated strawberry plant field sites will not contain commercial bee hives and will not be located immediately adjacent to fields containing commercial bee hives.
- ◆ No fruit or seed will be harvested from any non-regulated strawberry plant grown within 100 feet of a regulated strawberry plant.
- ◆ Transgenic fruit will be hand harvested at regular intervals to reduce dissemination of fruit and seed by foraging animals.
- ◆ Any strawberry plants grown within 100 feet of regulated strawberry plants will be treated as regulated plant material and will be disposed of as a regulated article, including destruction of all fruit and seed.
- ◆ Transgenic fruit shall not be tasted, consumed, sold, or placed in commercial distribution unless authorized in writing.

Volunteer Plants

- ◆ The field test plot will be monitored for volunteers through weather conditions that favor seed germination or plant establishment.
- ◆ Volunteers detected within the field site will be eliminated before flowering by herbicide treatment, hand weeding, or mechanical cultivation.

Observation and Monitoring Forms

- ◆ Field trial Observation and Post-harvesting Monitoring forms will be completed for each field trial of regulated plant materials and returned to Mr. X of the company to ensure compliance with USDA/APHIS regulations and facilitate future commercial approvals.

Sample of Generic Protocols for Notification Field Release of Genetically Engineered Pea (*Pisum sativum*)

Company X's policy requires compliance with the US Department of Agriculture, Animal and Plant Health Inspection Service (USDA/APHIS) regulations in 7 CFR Part 340 for the importation, interstate movement, and environmental release of all regulated plant materials. The principal investigator is responsible for complying with the following regulatory standards for conducting a field trial of genetically engineered pea.

**Shipping and
Maintenance at
Destination**

- ◆ Regulated plant materials shall be double packaged for shipping: they shall be packed in a sturdy inner bag or box surrounded by a sturdy outer bag or box. Both containers must be independently capable of preventing loss of the plant materials.
- ◆ Regulated seed shall be packed in marked containers labeled "TRANSGENIC."
- ◆ Shipping container of regulated plant materials shall be labeled with the contents (Containers Pea Seed) and the USDA Permit or Notification Number (USDA No. xx-xxx-xn)
- ◆ Regulated plant materials shall be segregated from non-regulated materials at all times to prevent accidental mixing.
- ◆ Regulated plant materials shall be planted in defined areas. The boundaries of the field trial shall be marked.
- ◆ All machinery used in the field trial that may retain reproductive plant parts shall be brushed clean of pod and plant material within the defined area for transgenic planting before use in another area.

**Identify and
Devitalization**

- ◆ Markers shall be placed in each container (pot, seed tray) or regulated plant materials in a greenhouse.
- ◆ Flags shall mark the boundaries of each planting of regulated plant materials in field trials and shall remain in place until the end of post-harvest monitoring to aid the detection of volunteers.
- ◆ Regulated plant materials from a contained facility shall be devitalized prior to disposal.
 - ❖ Reproductive plant parts (pollen, pod, seed) shall be collected and devitalized using dry heat or steam heat until non-viable, then composted or discarded as trash.
 - ❖ Non-reproductive plant parts (leaves, stems, roots) may be composted or discarded as trash.
- ◆ Regulated plant materials from a field trial may be disked into the soil for natural decay. The trial site shall be monitored for the presence of volunteers as prescribed below.

**Persistence in
the Environment**

- ◆ Regulated pea plants shall be physically isolated from other sexually compatible species by at least 25 feet. This based on the "Minimum Land, Isolation, Field and Seed Standards" adapted from Table 5, 7 CFR subpart 201.76. This is a distance adequate to prevent mechanical mixture in pea field.
- ◆ Any pods or seed harvested from any non-regulated pea plant grown within 25 feet of a regulated pea plant shall be treat as a regulated article.

Volunteer Plants

- ◆ Any pea plants grown within 25 feet of regulated pea plants shall be treated as regulated plant material and shall be disposed of as a regulated article, including destruction of all pods and seed.
- ◆ The field test plot shall be monitored for volunteers until the end of the next planting season.
- ◆ Features used to define the test plot shall remain in place until the end of the next planting season to aid in detection of volunteers.
- ◆ Volunteers detected within the field test shall be eliminated before flowering by herbicide treatment, hand weeding, or mechanical cultivation.

Observation and Monitoring

- ◆ Field Trial Observation and Post-harvest Monitoring forms will be completed for each field trial of regulated plant material and returned to Mr. X to ensure compliance with USDA/APHIS regulations and facilitate future commercial approvals.

Sample of Generic Protocols for Notification Field Release of Genetically Engineered Sunflower (*Helianthus annuus*)

**Shipping/
Receiving/
Storage**

- ◆ Check appropriate sources to ensure material and locations are listed in the permit.
- ◆ Do not ship if the state location is not listed in the permit.
- ◆ Two days prior to shipments in the State of Michigan, complete and send the Intent to Ship Genetically Modified Material.
- ◆ No shipping notice is needed if the county and State are listed on the permit.
- ◆ For most plant material, any shipping container consisting of an inner container that is a study bag, box, or other such structure, surrounded by an outer container that is also a sturdy bag, box, or other container would be each independently capable of preventing loss of shipped plant material.
- ◆ Each inner container (e.g., seed packet, box, bag of seed, or container of tissue samples) will be specifically labeled to identify it as containing transgenic material. This practice should avoid inadvertent mixing of transgenic with non-transgenic material.
- ◆ Place a copy of the USDA, APHIS approval letter in each shipment.
- ◆ Complete Transgenic Material Shipping Record; place a copy in the shipment, and send a copy to Regulatory Affairs Department.
- ◆ Complete and place a white shipping label on the outside container toward the right side of the address label.

Procedures

Sample of Site Specific Protocols (for Notification)

	<ul style="list-style-type: none">◆ Store genetically modified seed in a secure facility with a sign stating that regulated, genetically modified material is stored inside.
Planting	<ul style="list-style-type: none">◆ Two days prior to planting, complete and fax the Planting Notice. Seed may be planted by hand or machine. Ensure planters are cleaned thoroughly (completely free of transgenic seed) before using for non-transgenic seed.◆ Do not re-use seed packets.
Plot Management	Inspect trial at least every 4 weeks. Send completed Field Monitoring for Disease/Insect/Weediness Characteristic Form and send to Regulatory Affairs Department.
Pollinations	<ul style="list-style-type: none">◆ Bag flower heads or cage transgenic plants◆ Isolate distance of at least 2,640 feet (USDA minimum)
Harvest	<p>Two days prior to harvest, complete the Harvest/Destruct/Termination of Field Trial Notice and return to Regulatory Affairs Department.</p> <ul style="list-style-type: none">◆ Hand or machine harvest.◆ Store harvested seed in a clearly labeled and secure facility.◆ Return unwanted grain to field to be cultivated into the soil or burned.◆ Allow plants to dry down in the field and then cultivate.
Final Disposition of Regulated, Transgenic Material	<p>Acceptable methods are:</p> <ul style="list-style-type: none">◆ Cultivation into soil at the trial site◆ Incineration◆ Burial◆ Disposal at approval landfill after devitalization◆ Fermentation◆ Composting◆ Autoclaving and◆ Storage in a secure facility
Post Trial Monitoring	<ul style="list-style-type: none">◆ During the fallow period, the field should be watered to allow the germination of volunteer sunflowers. The site should be inspected for volunteers every 2 weeks until you have completed two monitoring where no volunteers have been found.◆ Volunteers can be destroyed by herbicide treatment, hand weeding, or cultivation.

Unintentional Release

- ◆ Complete Monitoring for Volunteer Plants Form and fax /send to Regulatory Affairs Department.
- ◆ The field should be planted to a crop other than sunflower.

Notify Biotechnology Regulatory Services immediately and in writing within 24 hours as soon as you know of any unintentional release of transgenic material. Unplanned releases also include vandalism or destruction of property.

Sample of Generic Protocols for Notification Field Release of Genetically Engineered Corn (*Maizzea mays* L.)

Shipping/ Receiving/ Storage

- ◆ Check appropriate sources to ensure material and location are listed in the permit.
- ◆ Do not ship if the State location is not listed in the permit.
- ◆ Complete and send the Ten Day Shipping/Planting Notice when the county shipping destination is not listed in the permit.
- ◆ Two days prior to shipment in the state of Michigan, complete and send the Intent to Ship Genetically Modified Material.
- ◆ No shipping notice is needed if the county and State are listed in the permit.
- ◆ For most plant material, any shipping container consisting of an inner container that is a sturdy bag, box, or other such structure, surrounded by an outer container that is also a sturdy bag, box, or other such structure would be acceptable under most circumstances. Bother inner container and outer container would be each independently capable of preventing loss of shipped plant material.
- ◆ Each inner container (e.g., seed packet, box, bag of seed, or container of tissue samples) will be specifically labeled to identify it as containing transgenic material. This practice should avoid inadvertent mixing of transgenic with non-transgenic material.
- ◆ Place a copy of the USDA, APHIS acknowledgment letter in each shipment.
- ◆ Complete Transgenic Material Shipping Record; place a copy in the shipment, and send a copy to Regulatory Sciences and Resources Department.
- ◆ Complete and place a white shipping label on the outer container toward the right side of the address label.
- ◆ Store genetically modified seed in a secure facility with a sign stating that regulated, genetically modified material is stored inside.

Procedures

Sample of Site Specific Protocols (for Notification)



Important

These conditions are in addition to normal phytosanitary and shipping conditions.

Planting

- ◆ DO NOT plant if the State planting location is not listed on the permit. Use the Seven Day Planting Notice when county and state planting location is listed in the permit. Use Ten Day Planting Notice when planting in a county not listed on the permit.
- ◆ Seed may be planted by hand or machine.
- ◆ Ensure planters are cleaned thoroughly (completely free of transgenic seed) before using for non-transgenic seed.
- ◆ Do not reuse seed packets.

Plot Management

Inspect trial at least every 4 weeks. Send completed field Monitoring for Disease/Insect/Weediness Characteristics Form.

Containment

- ◆ Cover all tassels at pollen shed and hand pollinate.
- ◆ Isolate by a distance of 660 feet and allow to open pollinate.
- ◆ Male sterility: Must be confirmed. Contact Regulatory Sciences and Resources with questions.

Harvest

- ◆ Seven days prior to harvest, complete and send the Harvest/Destruct Notice.
- ◆ Hand or machine harvest.
- ◆ Ensure all machinery (e.g., harvest machinery, dryers, etc.) are cleaned thoroughly (completely free of transgenic seed) before using for non-transgenic seed.
- ◆ Store harvested seed in a clearly labeled and secure facility.
- ◆ Allow plants to dry down in the field and then cultivate.

Final Disposition of Regulated, Transgenic Material

Acceptable methods are:

- ◆ Cultivation into soil at the trial site
- ◆ Incineration
- ◆ Burial
- ◆ Disposal at approved land fill **after devitalization**
- ◆ Fermentation
- ◆ Composting
- ◆ Autoclaving and
- ◆ Storage in a secure facility

Post Trial Monitoring

Mainland USA—The following growing season, monitor the trial site every 4 weeks for volunteers.

Hawaii and Puerto Rico—Monitor the trial site weekly, as soon as weather conditions are favorable or germination.

All sites—Continue to monitor until you have completed two inspections where no volunteers have been found.

- ◆ Volunteers can be destroyed by herbicide treatment, hand weeding, or mechanical cultivation.
- ◆ Complete and send Post-Trial Monitoring for Volunteer Plants.
- ◆ The following season, the field should be planted to a crop other than corn.
- ◆ Notify Biotechnology Regulatory Services immediately and in writing within 24 hours as soon as you know of any unplanned shipment or planting regulated, transgenic material.
- ◆ Unplanned releases also include vandalism or destruction of property.

Unplanned Release

Procedures

Sample of Site Specific Protocols (for Notification)

Training

Officers have mainly been trained to conduct notification and other permit inspections through a variety of methods.

In recent years PPQ Officers have been trained to conduct notification and permit inspection as follows:

- ◆ When on Developmental Assignments with the Regional Office
- ◆ During special seminars and workshops in the field with presentations on regulations and process by the RBT followed by a visit to one or more field sites
- ◆ At Compliance Training Workshops for PPQ Officers and Supervisors planned by PPQ, WR in liaison with BRS and with state universities such as Colorado State University and other institutions.
- ◆ During on-site training at active notification field sites by PPQ Officers in conjunction with RBT and by following background information furnished by the RBT.
- ◆ By using the Biotechnology Inspection Manual as a reference. Following manual revisions, new biotech policy and regulations can be found on the BRS web page.
- ◆ During self-training exercises on special topics. For example, BRS recently furnished compact discs with instructions for self-training in confidential business information (CBI) to PPQ Officers. **Ask your BRS Regional Biotechnologist (RBT) for training materials prior to handling CBI.**
- ◆ Because of the success with these pilots, additional video links are planned in the future for continuing education. On-site training of field officers is a major job responsibility of the Regional Program Manager in charge of the biotechnology program.

References and Contacts

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References

A wealth of up-to-date information is available from the internet at the addresses below. If you do not have direct internet access through Lotus Netscape Communicator, we provide a working list below that is mainly from the APHIS Biotech Permit Branch.

- ◆ APHIS Biotech Home Page, Permits Branch & Contents): How do I apply to import, move or field a genetically engineered organism? <http://www.aphis.usda.gov/brs/>
- ◆ A User's Guide to Notifications (overview) <http://www.aphis.usda.gov/brs/usergd.html>
- ◆ Biology of Crop Plants (7 major species) <http://www.aphis.usda.gov/brs/user.html>
- ◆ View Current Status of Application http://www.aphis.usda.gov/brs/application_status.html
- ◆ Virginia Tech, Information Systems for Biotech (administered by USDA's Cooperative State Research Service) with references, news, meetings, etc. <http://www.isb.vt.edu/>
- ◆ The regulation of transgenic arthropods <http://www.aphis.usda.gov/brs/arthropods.html>
- ◆ Other biotech web sites of US Government with links to USDA branches <http://www.aphis.usda.gov/brs/links.html#US>

The inspecting officer should consult any up-to-date college reference on Introduction to Plant Sciences or Botany to obtain basic background on general morphology, taxonomy, cell biology, microorganisms, and genetics.

- ◆ Library of Crop Technology Lesson Modules <http://croptechnology.unl.edu/>
- ◆ Transgenic Crops, An Introduction and Resource Guide <http://www.colostate.edu/programs/lifesciences/TransgenicCrops/index.html>

Additional general and advanced scientific information may be accessed by internet and at annual meetings of professional societies that involve biotechnology. Examples of Abstracts of articles in scientific journals below is online and free:

- ◆ Entomological Society of America (on line information including ESA branches, sections, position on transgenic insects, etc.)
<http://www.entsoc.org/about%5Fesa/>
- ◆ American Phytopathology Society (on line resources, i.e., position papers on plant pest management research, sustainable environment, etc.) <http://www.apsnet.org/>
- ◆ Ecological Society of America (has an all-electronic publication, Conservation Ecology, an education section, etc.)
<http://www.esa.org/>

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BRS Policy Coordination Division

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BRS Notification Request Submissions by email

<http://www.aphis.usda.gov/brs/emailnot.html>

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References and Contacts

Contacts

6

Biotechnology Manual

Permit Information

Although certain types of transgenic material can be moved interstate or field tested under a standard notification process, other transgenic material may be considered a higher risk. This higher risk material can be moved interstate or field tested only under a permit process. Inspection under permit will be covered in the next edition of the Biotechnology Manual. This section, sample documents, and forms relating to permits are included in this interim edition for your information and comment to help develop the next edition of the manual.

The following pages present background information on permit-related documents and supporting information. In the Procedure Section, we briefly discussed Biotechnology permits in addition to notification.

These pages present only information specifically for permits issued under Form 2000. Questions concerning these documents or support pages should first be directed to the Regional Program Manager (7RPM) responsible for the Biotechnology Program and secondly to the Biotechnology Permits Unit in Riverdale, MD at (301) 734-5787.

In order of importance, the officer should consider Form 2000 to be first. In the sample Form 2000 presented on the next page, note at the top of the page, it is designated the CBI-deleted copy which is to protect the applicant. The non-CBI copy is retained at the Biotech Permits office. The CBI information is furnished to the inspecting officer by the Region. The Form 2000 is always supported by Supplemental Permit Conditions, Standard Permit Conditions, and a Permit Approval Letter regardless of the kind of permit. Samples of each of these follows. The sample *Memo Inspection Request for a Release Site* is prepared by the Region to further assist the inspecting officer. Similarly, the worksheets for release and harvest are routinely furnished by the Region. The *Facility Inspection Checklist* is furnished to the officer from the Region by the RPM. As with notification, all permit reports are returned to the RPM before they are forwarded to the Riverdale, MD office.

After the Form 2000 and the related supplemental and standard permit conditions, the Facility Inspection Checklist is the most frequently used document by officers conducting permit inspections.

Supervisors and officers should be familiar with both of these documents if they are designated to conduct inspections on transgenic plant or arthropod material pursuant to APHIS permits.

Glossary

Accident—an unfortunate event resulting from carelessness, unawareness, ignorance, or a combination of incidents.

Acknowledged Notification—A notification is given the status of “acknowledged” by the USDA APHIS BRS after a formal review process. Once acknowledged, the notification is valid.

Administrator—The Administrator of the Animal and Plant Health Inspection Service (APHIS) or any other employee of APHIS to whom the authority has been or may be delegated to act in the Administrator's stead.

Adventitious Presence—The extrinsically added regulated article in nonregulated articles.

Amendments to the original notification—Rarely, a notification may contain amendments that are reviewed by the USDA APHIS BRS after the initial acknowledgement process. Amendments will describe changes to the conditions of the field trial that may be of importance in the inspection.

APHIS—Animal and Plant Health Inspection Service (APHIS). An agency of the United States Department of Agriculture.

Antecedent Organism—An organism that has already been the subject of a determination of nonregulated status by APHIS under 7 CFR 340.6, and that is used as a reference for comparison to the regulated article under consideration under these regulations.

Applicant Name—Name on the notification or permit of the person who has authored the notification or permit to the BRS.

Application—Organizations may submit an application for a permit to grow a regulated article in a field trial with BRS. See ‘permit’ for more information.

Autoclave—A machine used to sterilize laboratory equipment and raw materials using heat and pressure.

Bagging—See flower bagging.

Begin release—The date specified in a field test permit indicating when the field test may begin.

Biotechnology—The application of genetic techniques (manipulating genes to obtain certain favorable traits) to industrial, medical and agricultural organisms.

Border rows—The border rows are an area of land that is planted around the regulated article. If border rows are part of the field trial design, then anything growing in the border row must be treated as if it is the regulated article.

Border—A part that forms the outer edge of something, a boundary.

BRS—Biotechnology Regulatory Services (BRS). An agency of the United States Department of Agriculture, Animal and Plant Health Inspection Service.

Burial Pit—A hole or trench in which regulated articles are buried as a form of devitalization and/or disposal.

Cage—A structure for confining the regulated article, usually to prevent pollination, theft or damage.

CBI—Confidential business information.

Certified Foundation Seed—Foundation seed is handled as to maintain high levels of genetic purity and identity through a set of specific procedures; certification of the seed follows verification that procedures were followed in the seed production process.

CFR—The Code of Federal Regulations. The reference for all Code of Regulations related to notifications and permits is found in 7 CFR 340.

Compliance—observance of official requirements.

Compliance Officer—Any employee of the Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or State Cooperator authorized to undertake compliance activities related to 7 CFR 340, by the Administrator in accordance with law to enforce the provisions of this part.

Compliance Program Branch Chief—Any employee of the Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, authorized to oversee all compliance activities related to 7 CFR 340, by the Administrator in accordance with law to enforce the provisions of this part.

Container—A receptacle for containing the regulated article. Containers used will vary in size, shape, material and construction.

Cooperator—The person at the field trial location who is responsible for the maintenance of the field trial site. This person may be the same person who is listed on the notification, but it may also be someone who has been contracted or designated to grow and manage the field trial by the party listed on the notification.

Cultivation—Production of crops by preparing the land.

Deleterious—Harmful in a subtle or unexpected way.

Detailed procedures—See Standard Operating Procedures.

Deviation—a departure from what is prescribed or expected. Effective date the date when a permit granted under notification system becomes effective.

Devitalize—Rendering an organism (including tissue parts or seeds) unable to grow or reproduce.

Donor organism—The organism from which genetic material is obtained for transfer to the recipient organism.

Effective date—The date when a permit granted under the notification system becomes effective.

End release—the date specified in a field test permit indicating when the field test must end.

Environment—All the land, air, and water; and all living organisms in association with land, air and water.

Environmental Release—See ‘release into the environment’.

Facility —A temporary or permanent structure used for sheltering, storing and securing the regulated article, equipment and/or materials.

Fallow—An area of land that is traditionally plowed but not seeded for a season, and which may or may not be tilled or chemically treated for control of plants growing in it. In the case of field trials, a fallow zone may surround the outside of the area in which the regulated article is grown. With explicit written permission, the fallow zone may be planted with crops to reduce soil erosion (called cover crops). Anything growing in the fallow zone is to be treated as if it is the regulated article.

FDA—Food and Drug Administration. An agency of the Department of Health and Human Services.

Field Release—See ‘release in the environment’.

Field test—See ‘field trial’.

Field trial location—For any given notification, there may be several field trial locations in different states, and in different counties in a single state. Within a field trial location, there may be multiple field trial sites. Inspectors will usually be asked to undertake an inspection on one field trial location.

Field trial—The growth of regulated articles in a defined field area for the purposes of evaluation and testing.

Field trial site—For any given notification, there may be several field trial sites in a single field trial location. Field trial sites vary in size, from fractions of acres to hundreds of acres. The field trial site may be referred to by cooperators as plots or fields. Field trial sites are not described in a notification, and are determined by the inspector in communication with the notification holder. Inspectors will usually be asked to undertake an inspection on some or all of the field trial sites at a single field trial location.

Flower bagging—Bagging is the placement of specialized, durable plastic or waxed paper bags on the reproductive structures of plants in order to control pollination and fertilization. Plant breeders have developed formal procedures for the use of bagging in many crop types. Formal bagging procedures assure that the proper materials are used, the timing of the bagging is appropriate for the reproductive system of the plant, and that the bags are attached so as to remain on the plant through various environmental conditions.

Flower removal—Flower or flower part removal may be achieved through manual or chemical processes that render flowers unable to fertilize themselves or other plants. Plant breeders have developed formal procedures for the removal of flowers or flower parts in many crop types. Formal flower removal procedures assure that the proper

methods are used to achieve complete flower or flower part removal, and that the timing of the removal is appropriate for the reproductive system of the plant.

Flowering time—The time at which the plant is shedding pollen and/or receptive to pollination. This is generally days to weeks and is variable from species to species. See also 'temporal isolation'.

Free Living Plants—Plants that are not intentionally planted.

Gene—A hereditary unit that determines a characteristic in an organism by directing the formation of a specific protein.

Genetic engineering—The genetic modification of organisms by recombinant DNA techniques.

Genotype—The total genetic, or hereditary, constitution that an individual receives from its parents. An individual organism's genotype is distinguished from its phenotype, which is its appearance or observable character.

GEO—Genetically engineered organisms, developed using recombinant DNA techniques.

Global positioning system (GPS)—Global positioning systems are devices that calculate a geographic position and report that position in geographic coordinates.

GMO—Genetically modified organisms, developed using recombinant DNA techniques. Often used synonymously with GEO.

Inadvertent mixing—The mixture of the regulated article with nonregulated articles accidentally.

Incident—a singular and separate event that interrupts normal procedure.

Incursion—Entering into a defined space or area.

Inspection Authorization Number—The Biotechnology Regulatory Service Inspection Authorization Number (BRS IAN) is an accession and tracking number for every inspection done for BRS. The BRS IAN is different than the Notification Number. Every inspection will be assigned a BRS IAN.

Inspection Report—The formal documentation submitted by an Inspector following an inspection, including a summary report, worksheet, maps, photos and any other relevant documents obtained from the inspection.

Inspector—Any employee of the Animal and Plant Health Inspection Service, U.S. Department of Agriculture, or other person, authorized by the Administrator in accordance with law to enforce the provisions of this part.

Introduce or introduction—To move into or through the United States, to release into the environment, to move interstate, or any attempt thereat.

Isolation Distance—The distance required to prevent fertilization between two sexually compatible organisms.

Issue date—the date when a permit granted under the permitting process is issued **Location**—See field trial location.

Move (moving, movement)—To ship, offer for shipment, offer for entry, import, receive for transportation, carry, or otherwise transport or move, or allow to be moved into, through, or within the United States.

Notification—A notification is a procedure by which “certain regulated articles may be introduced without a permit, provided that the introduction is in compliance with the requirements” for notifications (7 CFR 340.3(a)). Only certain regulated articles are eligible for introduction under the notification procedures, as explained in 7 CFR 340.3(b).

Notification holder—The notification holder is the responsible person or party that applied for APHIS authorization to move or release a regulated article, and who is cited on the acknowledged notification from USDA APHIS BRS.

Notification number—Every notification has an APHIS-designated reference number, often referred to as the notification number. The APHIS-designated notification number is often listed as the ‘reference number’ in the notification letter that is generated by APHIS BRS. The applicant may also have their own, unique reference number for the notification.

Organism—Any active, infective, or dormant stage or life form of an entity characterized as living, including vertebrate and invertebrate animals, plants, bacteria, fungi, mycoplasmas, mycoplasma-like organisms, as well as entities such as viroids, viruses, or any entity characterized as living, related to the foregoing.

Organization—In addition to the notification holder, the notification may be related to an organization, such as a company, public or private university, or individual.

Performance standards—Field trials under notification must achieve six standards of performance in order to maintain compliance with federal regulations. The six standards are described in 7 CFR 340.3(c).

Permit Conditions—Conditions specified in a permit that is issued by the Administrator for the introduction of a regulated article as determined by the Administrator so as not to present a risk of plant pest introduction.

Permit—A written permit issued by the Administrator for the introduction of a regulated article under conditions determined by the Administrator not to present a risk of plant pest introduction.

Persistence—Continuance of the progeny of a regulated article in the environment beyond conditions approved in the notification or permit.

Person—Any individual, partnership, corporation, company, society, association, or other organized group.

PDF—Portable Document Format. PDF was invented by Adobe Systems and is a publicly available specification used by standards bodies around the world for secure, reliable electronic document distribution and exchange.

Pharmaceutical-Industrial Permit—A written permit issued by the Administrator for the introduction of a regulated article under conditions determined by the Administrator not to present a risk of plant pest introduction. According to Docket No. 3-038-1, these permits are specific to “plants that meet the following three criteria: (1) The plants are engineered to produce compounds that are new to the plant; (2) the new compound has not been commonly used in food or feed; and (3) the new compound is being expressed for non-food, non-feed industrial uses. Industrial uses include, but are not limited to, detergent manufacturing, paper production, and mineral recovery.”

Phenotype—The appearance or observable character that is the result of the expression of one or more genes.

Plant—Any living stage or form of any member of the plant kingdom including, but not limited to, eukaryotic algae, mosses, club mosses, ferns, angiosperms, gymnosperms, and lichens (which contain algae) including any parts (e.g. pollen, seeds, cells, tubers, stems) thereof, and any cellular components (e.g. plasmids, ribosomes, etc.) thereof. The taxonomic scheme for the plant kingdom is that found in Synopsis and Classification of Living Organisms by S.P. Parker, McGraw Hill (1984).

Plant Pest—Any living stage (including active and dormant forms) of insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof; viruses; or any organisms similar to or allied with any of the foregoing; or any infectious agents or substances, which can directly or indirectly injure or cause disease or damage in or to any plants or parts thereof, or any processed, manufactured, or other products of plants.

Pollination Distance—The maximum distance at which pollination can occur between two sexually compatible plants.

PPQ Officer—Any employee of Plant Protection & Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, authorized to undertake inspections by the Administrator in accordance with law to enforce the provisions of this part.

Procedure—A procedure is series of steps, and related processes, taken to accomplish a particular end. The series of steps may be described in a document or procedural manual. See 'standard operating procedure'. In a field trial, there may be procedures described for critical control points, such as planting, harvesting, storage and equipment cleaning. Each procedure may involve several specific processes. See 'process'.

Process—A process is the realization of steps to achieve a prescribed procedure. For example, in a field trial, several processes may be described to achieve the procedure of equipment cleaning, such as: select the site for cleaning operations, dismantle equipment, devitalize of seed removed from the equipment, and record the cleaning processes in a field trial notebook.

Product—Anything made by or from, or derived from an organism, living or dead.

Receive date—the date (or ranges of dates) when the application was received by APHIS BRS.

Recipient organism—The organism which receives genetic material

Reference number—See ‘notification number’.

Regional Biotechnologist (BRS)—Any employee of the Biotechnology Regulatory Services, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, authorized to coordinate compliance activities related to 7 CFR 340 at the regional level, by the Administrator in accordance with law to enforce the provisions of this part.

Regional Biotechnology Program Manager (PPQ)—Any employee of Plant Protection & Quarantine, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, authorized to coordinate compliance activities related to 7 CFR 340, by the Administrator in accordance with law to enforce the provisions of this part.

Regulated article: from 7 CFR 340.1—“Any organism which has been altered or produced through genetic engineering, if the donor organism, recipient organism, or vector or vector agent belongs to any general or taxa designated in 340.2 and meets the definition of plant pest, or is an unclassified organisms and/or an organism whose classification is unknown, or any product which contains such an organism, or any other organism or product altered or produced through genetic engineering which the Administrator, determines is a plant pest or has reason to believe is a plant pest. Excluded are recipient microorganisms which are not plant pests and which have resulted from the addition of genetic material from a donor organism where the material is well characterized and contains only non-coding regulatory regions.”

Release into the environment—The use of a regulated article outside the constraints of physical confinement that are found in a laboratory, contained greenhouse, or a fermenter or other contained structure.

Remedial Measures—Actions taken to minimize the consequences of an environmental problem.

Reproductive Parts—The parts of an organism capable of reproducing that organism constitute its reproductive parts. Plants have flowers that are made up of sexual organs, which can produce seed, but also may have vegetative reproductive parts, such as rhizomes, tubers and stolens.

Responsible person or party—The person who has control and will maintain control over the introduction of the regulated article and assure that all conditions contained in the permit and requirements in this part are complied with. A responsible person shall be a resident of the United States or designate an agent who is a resident of the United States.

Secretary—The Secretary of Agriculture, or any other officer or employee of the Department of Agriculture to whom authority to act in his/her stead has been or may hereafter be delegated.

Self-compliance—Actions taken by the responsible party to achieve and maintain compliance in the field trial.

Sexually compatible—Sexually compatible organisms are those that can fertilize or be fertilized by the regulated article so as to produce viable offspring.

Site—See field trial site.

Site-Specific protocols—Field trial protocols specific and unique to a particular site or location.

Standard operating procedures (SOPs)—In some instances, notification holders or responsible parties will develop and utilize formal Standard Operating Procedures for various processes in a field trial under notification. SOPs are not required for notifications, but if present, may be useful for the inspection process.

State—Any State, the District of Columbia, American Samoa, Guam, Northern Mariana Islands, Puerto Rico, the Virgin Islands of the United States, and any other Territories or Districts of the United States.

State regulatory official—State official with responsibilities for plant health, or any other duly designated State official, in the State where the introduction is to take place.

Supplemental notification conditions—Occasionally, a notification may contain supplemental conditions for the notification that may be reviewed by the USDA APHIS BRS during the initial formal review process. Supplemental notification conditions will describe additional or unique conditions for the field trial that may be of importance in inspection. Most supplemental notification conditions are those that are required by State Agriculture Officials.

Temporal isolation—Control of pollination and fertilization may be achieved in some species through the staggering of planting times of the regulated article relative to nearby sexually compatible organisms. Plant breeders have developed formal procedures for temporal isolation for many crop types. Formal temporal isolation procedures assure that the proper methods are used to achieve separation of flowering times over various environmental conditions and plant varieties.

Traditional permit—see ‘permit’.

Trait—A trait is a characteristic of an organism, seen at the level of the phenotype (the physical structure). Many traits are the result of the expression of a single gene, but some are polygenic result from the expression of more than one gene.

Transgenic—An organism that contains genetic material originally derived from an organism other than the parents.

Valid notification—A valid notification is one that has been acknowledged by USDA APHIS BRS through a formal review process, for a field trial process that is to occur for a specified time period.

Volunteer—Crop plants that are not planted, but that grow in planted crops, are considered ‘volunteers’, and are treated as weeds in crop production systems. Volunteer crops are usually present in a field because they were grown in that field in previous years, or because the seed was distributed to the field via wind, water, equipment, or wildlife. Most crops can produce volunteers in subsequent seasons.



Appendix A

Sample Forms and Documents

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This application is authorized by the Federal Plant Pest Act (7 U.S.C. 150aa et seq. and the Plant Quarantine Act (7 U.S.C. 151 et seq.)). The information will be used to determine eligibility to receive all types of permits. No permit shall be issued until this application has been approved.

U.S. DEPARTMENT OF AGRICULTURE
BIOTECHNOLOGY, BIOLOGICS, AND ENVIRONMENTAL PROTECTION
**APPLICATION FOR PERMIT OR
COURTESY PERMIT UNDER 7 CFR 340**
(Genetically Engineered Organisms or Products)

See reverse side for additional information

FORM APPROVED
OMB NO. -579-0085

INSTRUCTIONS: Complete this form and enclose the supporting materials listed on the reverse side. See page 3 for detailed instructions.

1. NAME AND ADDRESS OF APPLICANT		2. PERMIT REQUESTED ("X" one) <input type="checkbox"/> Limited - Interstate Movement <input type="checkbox"/> Limited - Importation <input type="checkbox"/> Release into the Environment <input type="checkbox"/> Country Permit	3. THIS REQUEST IS ("X" one) <input type="checkbox"/> New <input type="checkbox"/> Renewal <input type="checkbox"/> Supplemental
4. TELEPHONE NUMBER Area Code ()		5. MEANS OF MOVEMENT <input type="checkbox"/> Mail <input type="checkbox"/> Common Carrier <input type="checkbox"/> Baggage or Handcarried By whom _____	
6. GIVE THE FOLLOWING (if applicable; if more space is needed, attach additional sheet)			
Scientific Name		Common Name	Trade Name
Other Designation			
a. Donor Organism:			
b. Recipient Organism:			
c. Vector or Vector Agent:			
d. Regulated Organism or Product:			
e. If product, list names of constituents:			
7. QUANTITY OF REGULATED ARTICLE TO BE INTRODUCED AND PROPOSED SCHEDULE AND NUMBER OF INTRODUCTIONS		8. DATE (or inclusive dates of period) OF IMPORTATION, INTERSTATE MOVEMENT, OR RELEASE	
9. COUNTRY OR POINT OF ORIGIN OF THE REGULATED ARTICLE		10. PORT OF ARRIVAL, DESTINATION OF MOVEMENT, OR SPECIFIC LOCATION OF RELEASE	
11. ANY BIOLOGICAL MATERIAL (e.g., culture medium, or host material) ACCOMPANYING THE REGULATED ARTICLE DURING MOVEMENT			
12. APPLICANTS FOR A COURTESY PERMIT - STATE WHY YOU BELIEVE THE ORGANISM OR PRODUCT DOES NOT COME WITHIN THE DEFINITION OF A REGULATED ARTICLE			
13. SEE REVERSE SIDE			
I hereby certify that the information in the application and all attachments is complete and accurate to the best of my knowledge and belief. False Statement: Falsification of any item on this application may result in a fine of not more than \$10,000 or imprisonment for not more than 5 years or both. (18 U.S.C. 1001)			
14. SIGNATURE OF RESPONSIBLE PERSON		15. PRINTED NAME AND TITLE	16. DATE
FOR APHIS USE ONLY			
State Notification Letter Sent		State Review Received	Permit Issued <input type="checkbox"/> Yes <input type="checkbox"/> No
Date of Determination	Permit No.	No. of Permit Labels Issued	Supplemental Conditions Enclosed <input type="checkbox"/> Yes <input type="checkbox"/> No
Signature of BBEP Official		Date	Expiration Date

APHIS FORM 2000 (JUL 89) Replicates PPQ Form 1001 which may be used

FIGURE 8-2: APHIS Form 2000, Application for Permit or Courtesy Permit Under 7 CFR 340

Appendix A: Sample Forms and Documents
Contents


	ENCLOSURES	ENCLOSED ("X")	IF PREVIOUSLY SUBMITTED, LIST DATE & PERMIT NO.
a.	Names, addresses, and telephone numbers of the persons who developed and/or supplied the regulated article.		
b.	A description of the anticipated or actual expression of the altered genetic material in the regulated article and how that expression differs from the expression in the nonmodified parental organism (e.g., morphological or structural characteristics, physiological activities and processes, number of copies of inserted genetic material and the physical state of this material inside the recipient organism (integrated or extrachromosomal), products and secretions, growth characteristics).		
c.	A detailed description of the molecular biology of the system (e.g., donor-recipient-vector) which is or will be used to produce the regulated article.		
d.	Country and locality where the donor organism, recipient organism, and vector or vector agent were collected, developed and produced.		
e.	A detailed description of the purpose of the introduction of the regulated article including a detailed description of the proposed experimental and/or production design.		
f.	A detailed description of the processes, procedures, and safeguards which have been used or will be used in the country of origin and in the United States to prevent contamination, release, and dissemination in the production of the: donor organism; recipient organism; vector or vector agent; constituent of each regulated article which is a product; and regulated article.		
g.	A detailed description of the intended destination (including final and all intermediate destinations), uses, and/or distribution of the regulated article (e.g., greenhouses, laboratory, or growth chamber location; field trial location, pilot project location; production, propagation, and manufacture location; proposed sale and distribution location).		
h.	A detailed description of the proposed procedures, processes, and safeguards which will be used to prevent escape and dissemination of the regulated article at each of the intended destinations.		
i.	A detailed description of the proposed method of final disposition of the regulated article.		

Public reporting burden for this collection of information is estimated to average 5 hours per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Department of Agriculture, Clearance Officer, OIRM, Room 404-W, Washington, D.C. 20250; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, D.C. 20503.

APHIS FORM 2000 (Reverse)

FIGURE 8-3: APHIS Form 2000, Application for Permit or Courtesy Permit Under 7 CFR 340 (Reverse)

04-121-02r



United States
Department of
Agriculture

APHIS Supplemental Permit Conditions

Animal and
Plant Health
Inspection Service

Biotechnology
Regulatory
Services

4700 River Road, Unit 147
Riverdale, Maryland
20737-1236

SUPPLEMENTAL PERMIT CONDITIONS
FOR FIELD TESTS OF PLANTS ENGINEERED TO PRODUCE PHARMACEUTICALS
OR INDUSTRIAL PRODUCTS.
Permit: 04-121-02r, ProdiGene, corn

1) Compliance with Regulations
Any regulated article introduced not in compliance with the requirements of 7 CFR Part 340 or supplemental permit conditions, shall be subject to the immediate application of such remedial measures or safeguards as an inspector determines necessary, to prevent the introduction of a plant pest. The responsible party may be subject to fines or penalties as authorized by the Plant Protection Act.

This Permit (APHIS Form 2000) does not eliminate the permittee's legal responsibility to obtain all necessary Federal and State approvals, including: (1) for the use of any non-genetically engineered plant pest or pathogens as challenge inoculum; (2) plants, plant parts or seeds which are under existing Federal or State quarantine or restricted use; (3) experimental use of unregistered chemicals; and (4) food, feed, pharmacological, biologic or industrial use of regulated articles or their products and co-mingled plant material. In the latter case, depending on the use, reviews by APHIS, the U.S. Food and Drug Administration, or the U.S. Environmental Protection Agency may be necessary.

If the regulated article or associated host organism is found to have characteristics substantially different from those listed in the permit application or suffers an unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms), APHIS shall be notified as soon as possible but no later than within 5 working days. In such cases, notice should be sent to:

Animal and Plant Health Inspection Service (APHIS)
Chief, Biotechnology Permit Program Operations, Rm. 5B53
4700 River Road, Unit 147
Riverdale, MD 20737.

The procedures, processes and safeguards used to prevent escape, dissemination and persistence of the transgenic plant as described in the permit application, in APHIS-approved Standard Operating Procedures (SOP) and in the supplemental permit conditions must be strictly followed. The permittee must maintain records sufficient to verify compliance with these procedures, including information regarding who performed the activity. Persons performing such activities shall have received training as described in a training program submitted to and approved by APHIS. These records are subject to examination by APHIS. APHIS/BRS must be notified of any proposed changes to the protocol referenced in the permit application.

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FIGURE 8-4: Supplemental Permit Conditions, Page 1 of 5

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APHIS Supplemental Permit Conditions

2) Distance to Other Corn Plants

Permittee must ensure that any corn from previous seasons is harvested and removed in a radius of 0.25 mile of the transgenic corn plot, before the transgenic corn is sown. No corn can be grown within 1 mile (5,280 feet) of the field test site throughout the duration of any field test which involves open-pollinated corn. When pollen flow is controlled by placing bags around the corn tassels or by the use of male sterile plants and detasseling, there will be no other corn with 2,640 feet of the field test site, and the pharmaceutical corn must be planted no less than 28 days before or 28 days after any corn growing in a zone extending from 2,640 to 5,280 feet from the field test site. When pollen flow is controlled by the use of male sterile plants and detasseling, detasseling must be performed at least every 48 hours during the period of time of tassel emergence. Test plots will be monitored as stated in the permit application to ensure that plants are not flowering.

3) Weeds

Weeds in the field test plot will be controlled by herbicide treatment or by hand rouging.

4) Perimeter Fallow Zone

To ensure that transgenic plants are not inadvertently commingled with plants to be used for food or feed, a perimeter fallow zone of at least 50 ft. must be maintained around the transgenic test site in which no crops are grown that will be harvested or used for food or feed. The perimeter fallow zone must start outside of any permitted border rows of non-transgenic plants that are the same as, or sexually-compatible with, the regulated article, and it shall be managed in such a way as to allow detection and destruction of volunteer plants that are the same as or sexually compatible with the transgenic plants.

5) Dedicated Planting and Harvesting Equipment

To ensure that regulated articles are not inadvertently removed from the site, planting and harvesting equipment must be dedicated to use in the permitted test site(s) from the time of planting through the end of harvesting. After this time, APHIS authorization will not be required for this equipment to be used on APHIS-permitted sites planted to the same types of transgenic crops as authorized under this permit (e.g. the same or different sites planted to the same crop with the same target protein(s) in subsequent growing seasons under an extension of this permit or a different permit), but authorization will be required from APHIS before this planting and harvesting equipment can be used on sites planted to crops not included under this permit. In the latter case, the permittee must notify APHIS/BRS and the PPQ Regional Biotechnologist and State Regulatory Official at least 21 calendar days in advance of cleaning this equipment for this purpose so that APHIS may schedule an inspection to ensure that the equipment has been cleaned appropriately.

6) Cleaning of Equipment

To minimize the risk of seed movement and commingling, equipment used for planting and harvesting, as well as other field equipment (e.g. tractors and tillage attachments, such as disks, plows, harrows and subsoilers) used at any time from the time of planting through the post-harvest monitoring period must be cleaned in accordance with procedures submitted to and approved by APHIS before they are moved off of the test site. Equipment used to transport harvested material must also be cleaned prior to loading and after transportation to

FIGURE 8-5: Supplemental Permit Conditions, Page 2 of 5

04-121-02r	APHIS Supplemental Permit Conditions
<p>the authorized site in accordance with procedures submitted to and approved by APHIS. Seed cleaning and drying must also be performed in accordance with the procedures submitted to and approved by APHIS so as to confine the plant material and minimize the risk of seed loss, spillage or commingling.</p>	
<p>7) Use of Dedicated Storage Facilities Dedicated facilities (locked or secured buildings, bins or areas, posted as restricted to authorized personnel only) must be used for storage of equipment and regulated articles for the duration of the field test. Before these facilities are returned to general use, they must be cleaned in accordance with procedures submitted to and approved by APHIS. In this case, the permittee must notify APHIS/BRS, the PPQ Regional Biotechnologist and State Regulatory Official at least 21 calendar days in advance of cleaning facilities for return to general use so that APHIS may schedule an inspection to ensure that the facilities have been cleaned appropriately.</p>	
<p>8) Post Harvest Monitoring The field test site which includes the perimeter fallow zone must be monitored for the presence of corn plants for one year after termination of the field test. All volunteer corn plants will be rendered non-viable by turning into the soil or by herbicide treatment and then turning into the soil.</p>	
<p>9) Post Harvest Land Use Restrictions Production of any food or feed crop not specifically designated in the permit at the field test site and the perimeter fallow zone is restricted during the growing season that follows harvest or termination of the field test.</p>	
<p>10) Reports and Confidential Business Information Confidential Business Information (CBI) will be handled according to the APHIS policy statement at 50 F.R. 38561-63.</p>	
<p>Planting Report Within 28 calendar days after planting, the permittee must submit a planting report that includes the following information for each field test site:</p> <ul style="list-style-type: none">A. A map of the site, with sufficient information to locate it, that includes: the GPS coordinates for each corner of the plot (inclusive of the border rows of any sexually compatible plants).B. The location and the approximate number and/or acres of transgenic plants which were actually planted at the test site for each of the target proteins.C. The total acreage of the test plot (exclude border rows, if any).D. The distance from the genetically engineered plants to the nearest corn plants. <p>Fax the planting report to the following APHIS personnel:</p> <ul style="list-style-type: none">A. The Chief, Biotechnology Risk Assessment Staff, Mr. Juan Roman, (301) 734-8669B. The PPQ Regional Biotechnologist (Dr. Ralph Stoaks, (970)-494-7576C. The State Regulatory Official, State of Texas (CBI-Deleted copy only), Mr. Robert Crocker, (512)-463-8225.	
3	

FIGURE 8-6: Supplemental Permit Conditions, Page 3 of 5

04-121-02r	APHIS Supplemental Permit Conditions
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Provide APHIS with the contact information for each field test site and indicate if planting and harvesting equipment will be moved between authorized field test sites.

Contact information for the APHIS PPQ Regional Biotechnologists is included on the attached map and for the APHIS State Plant Health Director at <http://www.aphis.usda.gov/travel/aqi.html>.

11) Termination Report
At least 21 calendar days before the anticipated harvest/termination of the field test. The permittee is required to notify the APHIS/BRS Permits office and the appropriate PPQ Regional Biotechnologist and State Regulatory Official(s) (<http://www.aphis.usda.gov/brs/regbiot.html>).

12) Field Test Data Report
Within 6 months after the end of the field test (final harvest or crop destruction), the permittee is required to submit a field test data report to the BRS Permits office. Field test reports shall include: methods of observation, resulting data and analysis regarding all deleterious effects on plants, nontarget organisms or the environment.

13) Monitoring Report
Post-harvest/post-season monitoring report must be submitted within 3 months after the end of the monitoring period that includes the dates the field site and perimeter fallow zone were inspected for volunteers, the number of volunteers observed and the actions taken.

14) Unauthorized Release
APHIS shall be notified orally immediately upon discovery and in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article.
For immediate oral notification, contact the following APHIS staff in the order indicated below.
APHIS BRS Deputy Administrator's office [phone number: (301) 734-7324]. Indicate that you wish to report an unauthorized or accidental release of a regulated article to the BRS Regulatory Division Director; or in that person's absence, to the Chief of either the BRS Biotechnology Permit Program Operations staff or the Biotechnology Risk Assessment staff, or the permit reviewer. In the event that one of these persons cannot be reached, contact:
The appropriate APHIS PPQ Regional Biotechnologist: Dr. Ralph Stoaks, (970)-494-7500.
The appropriate APHIS State Plant Health Director: Mr. Robert Crocker, Coordinator for Pest Management and Citrus Programs, Texas Department of Agriculture, Stephen F. Austin Building, 1700 N Congress, Austin, TX 78701. Tel: (512) 463-6332, Fax: (512) 463-8225

Contact information is maintained at the APHIS Biotechnology Regulatory Services website at <http://www.aphis.usda.gov/brs/regulatory.html>

Unless otherwise directed, written notification should be sent to:
Animal and Plant Health Inspection Service (APHIS)
BRS Regulatory Division (2) Director, Rm. 5B54
4700 River Rd. Unit 147
Riverdale, MD 20737

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FIGURE 8-7: Supplemental Permit Conditions, Page 4 of 5

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APHIS Supplemental Permit Conditions

15) Inspections
APHIS/Biotechnology Regulatory Services (BRS) and/or an APHIS/PPQ Regional Biotechnologist or APHIS State Plant Health Director may conduct inspections of the test site, facilities and/or records at any time. APHIS may invite the FDA or State Regulatory Officials to participate in these inspections. Inspections will likely correspond to the beginning of the field test, mid-season or during flowering, at and/or following harvest, and during the post-harvest monitoring period. Inspections will include examination of records that verify compliance with regulations and SOPs.

16) Inspections
APHIS's Biotechnology Regulatory Services (BRS) and/or an APHIS/PPQ Regional Biotechnologist or APHIS State Plant Health Director may conduct inspections of the test site, facilities and/or records at any time. APHIS may invite the FDA or State Regulatory Officials to participate in these inspections. Inspections will likely correspond to the beginning of the field test, mid-season or during flowering, harvest and/or following harvest, and during the post-harvest monitoring period. Inspections will include examination of records that verify compliance with regulations and SOPs.

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FIGURE 8-8: Supplemental Permit Conditions, Page 5 of 5

**Standard Permit Conditions
For the Introduction of a
Regulated Article
(7 CFR 340.3(f))**

Permit Conditions: A person who is issued a permit and his/her employees or agents shall comply with the following conditions, and any supplemental conditions which shall be listed on the permit, as deemed by the Deputy Administrator to be necessary to prevent the dissemination and establishment of plant pests:

- (1) The regulated article shall be maintained and disposed of (when necessary) in a manner so as to prevent the dissemination and establishment of plant pests.*
- (2) All packing material, shipping containers, and any other material accompanying the regulated article shall be treated or disposed of in such a manner so as to prevent the dissemination and establishment of plant pests.*
- (3) The regulated article shall be kept separate from other organisms, except as specifically allowed in the permit.*
- (4) The regulated article shall be maintained only in areas and premises specified in the permit.*
- (5) An inspector shall be allowed access, during regular business hours, to the place where the regulated article is located and to any records relating to the introduction of a regulated article.*
- (6) The regulated article shall, when possible, be kept identified with a label showing the name of the regulated article, and the date of importation.*
- (7) The regulated article shall be subject to the application of measures determined by the Deputy Administrator to be necessary to prevent the accidental or unauthorized release of the regulated article.*
- (8) The regulated article shall be subject to the application of remedial measures (including disposal) determined by the Deputy Administrator to be necessary to prevent spread of plant pests.*
- (9) A person who has been issued a permit shall submit to Biotechnology, Biologics, and Environmental Protection monitoring reports on the performance characteristics of the regulated article, in accordance with any monitoring reporting requirements that may be specified in a permit.*
- (10) Biotechnology, Biologics, and Environmental Protection shall be notified within the time periods and manner specified below, in the event of the following occurrences:*
 - (i) Orally notified immediately upon discovery and notify in writing within 24 hours in the event of any accidental or unauthorized release of the regulated article;*
 - (ii) In writing as soon as possible but not later than within 5 working days if the regulated article or associated host organism is found to have characteristics substantially different from those listed in the application for a permit or suffers any unusual occurrence (excessive mortality or morbidity, or unanticipated effect on non-target organisms);*
- (11) A permittee or his/her agent and any person who seeks to import a regulated article into the United States shall:*
 - (i) Import or offer the regulated article for entry only at a port of entry which is designated by an asterisk in 7 CFR 319.37-14(b);*
 - (ii) Notify Biotechnology, Biologics, and Environmental Protection promptly upon arrival of any regulated article at a port of entry, of its arrival by such means as a manifest, customs entry document, commercial invoice, waybill, a broker's document, or a notice form provided for such purpose; and*
 - (iii) Mark and identify the regulated article in accordance with 7 CFR 340.5.*

FIGURE 8-9: Standard Permit Conditions Page 1 of 1

Sample Notification Response from Biotechnology Evaluation

May 8, 1995

Applicant
Company
Address
City, MO 0000000

Dear Applicant:

Your notification request number (0000000) 00-000-00N, requesting permission to move interstate the regulated article xxxxxxxx, under 7 CFR 340.3 (c) is acknowledged. The notification will become effective and may be executed on or after May 8, 1995.

You must comply with the performance standards as stated in 7 CFR 340.3 (c). All packages must be clearly labelled as to content, and notification number must be prominently displayed on package.

The State of California concurs with APHIS determination, provided all requirements of 7CFR 301.85, Golden Nematode Quarantine are met.

The State of Hawaii concurs with APHIS determination, with the attached recommendations.

The State of Maine has attached supplemental conditions for movement and field release of regulated article.

Transgenic plants and organisms will not be shipped from this facility without notification and prior approval from the Michigan Department of Agriculture.

The State of North Carolina concurs based on .0303 (a)(7), of the North Carolina Administrative Code, a general permit provides for this release in North Carolina.

A copy of this letter of acknowledgement will be sent to the receiving State Regulatory Officials, and the Regional Operations Officer.

Sincerely,

Mary Jackson, Regulatory Specialist
Biotechnology Program Operations
Regulatory Division
Biotechnology Regulatory Services

Enclosure

cc:

B. Hass, California Dept. of Food and Agric., Sacramento, CA
L. Zermuehelen, Colorado Dept. of Agric., Lakewood, CO

FIGURE 8-10: Sample Notification Response from Biotechnology Evaluation

Sample Release Notification Letter

(copy and paste into your word processor and submit on your letterhead)

Permits Branch
Biotechnology Permits
Biotechnology Regulatory Services
4700 River Road, Unit 147
Riverdale, MD 20737-1228
FAX 301-734-8910

1. Reference Number: (leave blank for APHIS' use)

2. Applicant Reference Number:

3. Applicant/Responsible party:
Ma's Potatoes, Inc. Dr. Ida Solanum
1992 Tuberousum Dr. (315) 789-1011
Tatertown, NY 12345 fax (315) 789-1213

4. Duration of Introduction:
Release: February 21—September 1, 2004

5. Recipient: Potato, *Solanum tuberosum* cultivar Russet Burbank

6. Regulated Article: (see page 15 for other examples)

- a) designation of transformed line: VR67
category: VR
phenotype: PVY resistant
construct: pCP123
genotype:
promoter: enhanced 35S 5' from cauliflower mosaic virus (CaMV)
gene: anti-sense coat protein from PVY, strain O
enhancer: alcohol dehydrogenase (adh) intron 1 from *Zea mays*
terminator: nopaline synthase (nos) 3'
from *Agrobacterium tumefaciens* T-DNA
selectable marker -
promoter: 35S 5' from CaMV
gene: phosphinothricin acetyltransferase (bar)
from *Streptomyces hygrosopicus*
terminator: nos 3' from *A. tumefaciens* T-DNA
- b) designation of transformed line: VR19
category: VR
phenotype: PVY resistant
construct: pCP456
genotype:
promoter: 35S 5' from CaMV
gene: coat protein from PVY, strain O
terminator: nos 3' from *A. tumefaciens* T-DNA
selectable marker:
Promoter: 35S 5' from CaMV

FIGURE 8-11: Sample Release Notification Letter, Page 1 of 2

gene: -glucuronidase (uidA) from E. coli
terminator: 35S 3' from CaMV
promoter: 35S 5' from CaMV
gene: neomycin phosphotransferase (nptII) from E. coli Tn5
terminator: 35S 3' from CaMV

c) designation of transformed line: VR327
category: VR
phenotype: PVY resistant
construct: pCP123 and pCP456
genotype: (see descriptions above)

7. Mode of Transformation:
disarmed *A. tumefaciens* for line VR67;
electroporation for line VR19;
microprojectile bombardment for line VR327

8. Introduction:

Release:
NUMBER OF STATES/TERRITORIES AND SITES: ID(1), ME(1), WI(1)
Russ Burbank's Farm, 1776 Yukon Lane, Taber,
Bingham County, ID, 83221, 1.5 acres;
Pa's Potato Farm, 2004 Chippewa Rd.,
Baker Hill, Hancock County, ME, 04469, 1 acre;
Potato Research Farm, 56 Colby Drive,
Alva Lake, Oneida County, WI, 53777, 1 acre

9. Certification: I certify that the regulated article will be
introduced in accordance with the eligibility criteria and the
performance standards set forth in 7 CFR 340.3. The above information
is true to the best of our knowledge.
If there are any changes, we will contact APHIS.

Signature _____ Date _____
Name Typed _____

FIGURE 8-12: Sample Release Notification Letter, Page 2 of 2

Table of Important Biotech Permit Dates & Protocols to be reported by Permittee				
	Traditional Permit	PMP/PMI* Permit	Notification	Comprehensive
Planting Notice	7 days- Notify Region, State, BRS	7 days- Notify Region, State, BRS	N/A	10 days- Notify Region and State
Post-Planting Report	N/A	28 days- Notify Region, State, BRS	N/A	N/A
Harvest Notice	7 days- Notify Region, State, BRS	21 days- Notify Region, State, BRS	N/A	10 days- Notify Region and State
Field Data Report	6 months after trial harvest or termination	6 months after trial harvest or termination	6 months after trial harvest or termination	6 months after trial harvest or termination
Volunteer Monitoring	Per supplemental conditions	Per supplemental conditions	Per supplemental conditions	Per supplemental conditions
Pharm Monitoring Report	N/A	3 months after monitoring	N/A	N/A
Notice of intent to clean dedicated equipment or facility for return to general use	N/A	21 days- Notify Region, State, BRS	N/A	N/A
Emergency	Within 24hrs- Notify Region, State, BRS	Within 24hrs- Notify Region, State, BRS	Within 24hrs- Notify Region, State, BRS	Within 24hrs- Notify Region, State, BRS

*PMP- Plant made pharmaceutical
PMI- Plant made industrial

FIGURE 8-13: Important Biotech Permit Reporting Dates

Western Region
Biotechnology Permit
Field Release Report Worksheet
For traditional and comprehensive permit inspections
When completed, this is an Internal PPQ Document, Contains CBI

Permit Number: _____ Crop: _____
 Organization/Company: _____
 Responsible Applicant: _____
 Cooperator Contact Person: _____ Phone: _____
 Location of site & GPS Coordinates: _____ Date of Inspection _____
 Type of location: Farm ☐ Nursery ☐ Other (describe) _____

1. Cooperator had copy of permit and conditions? Y ☐ N ☐
 2. Were volunteer plants found from a previous field release? Y ☐ N ☐
 If yes, Number of volunteers _____,
 crop _____, permit number _____
 3. Was plot specific location according to permit? Y ☐ N ☐
 4. Was security according to permit protocol? Y ☐ N ☐
 5. Were plot dimensions according to permit? ☐ ☐
 6. What was on each side of test plot?
 North _____ East _____
 South _____ West _____
 7. Border buffer area required? Y ☐ N ☐
 If yes, How much? _____
 8. Were special permit conditions met? Y ☐ N ☐
 9. Was the seed storage area inspected? Y ☐ N ☐
 10. Were shipping containers inspected? Y ☐ N ☐
 11. Number of regulated articles released _____
 Number of phenotypes tested _____
 12. Describe disposal of any extra seeds or plants _____
 13. Was equipment cleaned of seed and plant material? Y ☐ N ☐
 If no, explain in cover memo _____
 14. Were any violations or discrepancies found? Y ☐ N ☐

Revised
06/28/04

FIGURE 8-14: Field Release Report Worksheet, Page 1 of 2

Inspecting Officer Signature: _____
Printed Name: _____
Phone: _____ Location of PPQ Officer: _____
Names and Affiliation of Any Other Persons at the inspection: _____

(Report due 10 days after field release)

The signed original of this report was furnished to Juan Roman, APHIS, BRS Y ☐ N ☐

Please fax/ email completed worksheet to:
Ralph Stoaks, Regional Biotechnologist
2150 Centre Ave. Bldg. B, 3E10
Ft. Collins, CO 80526
Phone: 970-494-7573 Fax: 970-494-7576
Email: ralph.d.stoaks@aphis.usda.gov

Please FedEx original worksheet to:
Juan Roman, Chief Biotechnology Program Operations
4700 River Road, Unit 147, 5B53
Riverdale, MD 20737
Phone: 301-734-0029

Revised
06/28/04

FIGURE 8-15: Field Release Report Worksheet, Page 2 of 2

HARVEST REPORT WORKSHEET	
For traditional and comprehensive permit inspections	
<i>When completed, this is an Internal PPQ Document</i>	
Permit Number _____	Crop _____
Organization/Company _____	Location _____
Date of PPQ notified of Harvest _____	Actual Harvest Date _____
Date of Harvest inspection _____	
1. Was the crop terminated?	Y <input type="checkbox"/> N <input type="checkbox"/>
2. Describe method of disposal of regulated: (plant debris, seeds, fruit, tubers, plant parts, etc.)	

3. Was the equipment cleaned of seed and plant material?	Y <input type="checkbox"/> N <input type="checkbox"/>
4. Were regulated articles shipped out of state?	Y <input type="checkbox"/> N <input type="checkbox"/>
If yes where? _____	
5. Was there an APHIS permit/certificate number to ship from state?	<input type="checkbox"/> Y <input type="checkbox"/> N
6. Does the permit require more monitoring by applicant?	Y <input type="checkbox"/> N <input type="checkbox"/>
7. Does the cooperator agree to monitor and destroy volunteers?	Y <input type="checkbox"/> N <input type="checkbox"/>
8. Did the applicant comply with all permit conditions?	Y <input type="checkbox"/> N <input type="checkbox"/>
If no, explain in cover page memo.	
The signed original of this report was furnished to Juan Roman, APHIS, BRS	
Y <input type="checkbox"/> N <input type="checkbox"/>	
Inspecting Officer Signature: _____	
Printed Name: _____	
Phone _____	Location of PPQ Officer _____
<i>(Report due 10 days after Harvest or Termination of crop)</i>	
Please fax/ email completed worksheet to: Ralph Stoaks, Regional Biotechnologist 2150 Centre Ave. Bldg. B, 3E10 Ft. Collins, CO 80526 Phone: 970-494-7573 Fax: 970-494-7576 Email: ralph.d.stoaks@aphis.usda.gov	Please FedEx original worksheet to: Juan Roman, Chief Biotechnology Program Operations 4700 River Road, Unit 147, 5B53 Riverdale, MD 20737 Phone: 301-734-0029
Revised 06/28/04	

FIGURE 8-16: Harvest Report Worksheet, Page 1 of 1

Pharmaceutical/Industrial Pre-Planting Report Worksheet	
<i>When completed, this is an Internal PPQ Document</i>	
Permit Number: _____	Crop: _____
Organization/Company: _____	
Responsible Applicant: _____	
Cooperator Contact Person: _____	Phone: _____
Location & GIS/ GPS Coordinates: _____	
Type of location: Farm <input type="checkbox"/> Nursery <input type="checkbox"/> Other (describe) _____	
Date of Inspection _____	
 Site information:	
1. <u>Indicate which party is responsible</u>	<u>Actual/Planned Training Date</u>
Planting _____	_____
Crop maintenance _____	_____
Flower de-tasseling/bagging _____	_____
Harvesting _____	_____
Dedicated equipment cleaning _____	_____
Volunteer monitoring/destruction _____	_____
2. Cooperator had copy of permit conditions Y <input type="checkbox"/> N <input type="checkbox"/>	
3. Is there documentation that ALL of these parties have received training relative to performing these activities according to an APHIS-approved training program? Y <input type="checkbox"/> N <input type="checkbox"/>	
4. Was a site map obtained or drawn by you for reference? Y <input type="checkbox"/> N <input type="checkbox"/>	
5. Was acreage and site location according to permit? Y <input type="checkbox"/> N <input type="checkbox"/>	
6. Is there sufficient space for a 50 ft. perimeter fallow zone provided? Y <input type="checkbox"/> N <input type="checkbox"/>	
7. Indicate what is or was proposed on each side of the planting site outside of the fallow zone. If it is a crop, indicate whether it has been planted.	
East _____	West _____
North _____	South _____
8. Were volunteer crop plants detected in the proposed site and fallow zone? Y <input type="checkbox"/> N <input type="checkbox"/>	
If Yes: # of Volunteers found _____	Plant Name _____
Site <input type="checkbox"/> Fallow <input type="checkbox"/>	Isolation zone <input type="checkbox"/>
9. Is the reproductive isolation distance consistent with the permit conditions? Y <input type="checkbox"/> N <input type="checkbox"/>	
10. Is there a secure, dedicated seed storage area or facility? Y <input type="checkbox"/> N <input type="checkbox"/>	
11. Is this field equipment being stored in a locked and restricted dedicated facility? Y <input type="checkbox"/> N <input type="checkbox"/>	
Revised 06/28/04	

FIGURE 8-17: Pharmaceutical/Industrial Pre-Planting Report Worksheet, Page 1 of 3

12. Is site security as stated in the permit, and are facilities locked with restricted access? Y ☐ N ☐

13. Does record book have entries for dates, times, & names for planting and harvest notices to PPQ, planting, flowering, harvesting, volunteer monitoring, dedicated equipment use, cleaning and movement, and similar critical activities? Y ☐ N ☐

14. Was permittee advised that they must notify PPQ WR, BRS, and State Plant Regulatory Officials 7 calendar days before planting, 21 calendar days before the anticipated harvest, and 21 days before cleaning dedicated equipment for return to general use to schedule inspections? And, were they advised the post-planting report is due 28 days after planting? Y ☐ N ☐

15. Report contains a significant deficiency Y ☐ N ☐

Inspecting Officer Signature: _____ Printed Name: _____
Phone: _____
Location of PPQ Officer: _____
Names and Affiliation of Any Other Persons at the inspection: _____

The signed original of this report was furnished to Juan Roman, APHIS, BRS Y ☐ N ☐

Inspection Reporting:
Report due 5 business days after inspection.
Use cover page to report violations.
Report deficiencies within 24 hrs to Regional Biotechnologist

<p><i>Please fax/ email completed worksheet to:</i> Ralph Stoaks, Regional Biotechnologist 2150 Centre Ave. Bldg. B, 3E10 Ft. Collins, CO 80526 Phone: 970-494-7573 Fax: 970-494-7576 Email: ralph.d.stoaks@aphis.usda.gov</p>	<p><i>Please FedEx original worksheet to:</i> Juan Roman, Chief Biotechnology Program Operations 4700 River Road, Unit 147, 5B53 Riverdale, MD 20737 Phone: 301-734-0029</p>
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Remind cooperator of the following:
1) Federal Register Notice of March 10, 2003 stipulates that No Food or Feed Crops can be Grown or Harvested on field test site and fallow zone during the growing season for the test crop.
2) In case of accidental or unauthorized release, FR Notice stipulates that no food or feed crops can be grown or harvested on field test site and fallow zone during post-season monitoring period unless specific authorization to do so has been obtained from APHIS, BRS.

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FIGURE 8-18: Pharmaceutical/Industrial Pre-Planting Report Worksheet, Page 2 of 3

3) PPQ, BRS, and State Plant Regulatory Officials must be notified in case of accidental or unauthorized release (e.g., seed loss, theft or vandalism, volunteer plants that are allowed to flower during the monitoring period,) notification must be made (within 24 hrs) to APHIS. Contact APHIS BRS Deputy Administrator's office, (301) 734-7324 or -5745, or (202) 720-4383 and indicate that you wish to report accidental release to BRS Regulatory Division Director.

4) PPQ, BRS, and State Plant Regulatory Officials must be notified at least 21 calendar days before cleaning dedicated equipment for return to general use to schedule inspections.

5) A volunteer monitoring report must be submitted within 3 months after the end of the monitoring period.

Revised
06/28/04

FIGURE 8-19: Pharmaceutical/Industrial Pre-Planting Report Worksheet, Page 3 of 3

Pharmaceutical/Industrial Release Report Worksheet

When completed, this is an Internal PPQ Document

Permit Number: _____ Crop: _____

Organization/Company: _____

Responsible Applicant: _____

Cooperator Contact Person: _____ Phone: _____

Location & GIS/ GPS Coordinates: _____

Type of location: Farm ☐ Greenhouse ☐ Other (describe) _____

Date of Inspection _____

Site information: Check records and facilities and verify the following

1. Cooperator had copy of permit conditions Y ☐ N ☐
2. Names and dates of person performing the planting are recorded Y ☐ N ☐
3. Dedicated planting equipment was used Y ☐ N ☐

If Yes, Enter make, model, and identifying # _____

4. Planter was cleaned within 48 hrs of leaving the test site according to SOP Y ☐ N ☐
5. The person cleaning the planter was trained in this SOP Y ☐ N ☐
6. Volume, number, or acres and location of each regulated plant line planted was recorded Y ☐ N ☐

How many lines were planted? _____

7. Is there a secure, dedicated seed storage area or facility? Y ☐ N ☐
8. Planter was stored in a locked, restricted dedicated storage facility Y ☐ N ☐
9. If planter is to be used on another site authorized under this permit, have APHIS, BRS and PPQ been notified? N/A ☐ Y ☐ N ☐
10. Was a site map obtained or drawn by you for reference? Y ☐ N ☐
11. Was acreage and site location according to permit? Y ☐ N ☐
12. Is the 50 ft. fallow zone, devoid of food or feed crops? Y ☐ N ☐

13. Number of volunteers found in field test site, fallow or isolation zone _____

Plant Name _____ N/A ☐

14. If the volunteers are the same as or sexually compatible to the transgenic crop grown, indicate flowering: has occurred ☐ is occurring ☐ is just about to occur ☐

15. Are crops of the same or sexually compatible species currently being grown closer than the isolation distance specified in the permit for the transgenic crop? Y ☐ N ☐

Distance _____

If volunteers are present (#13) and either #14 or #15 are checked, document with GPS & digital photos and **IMMEDIATELY NOTIFY THE APHIS BRS REGULATORY DIVISION DIRECTOR** for guidance on further action (301) 734-7324 or -5745, or (202) 720-4383.

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FIGURE 8-20: Pharmaceutical/Industrial Release Report Worksheet, Page 1 of 3

16. Indicate what is (or was proposed) on each side of the planting site outside of the fallow zone. If it is a crop, indicate whether it has been planted.

North _____ East _____
South _____ West _____

17. Is the reproductive isolation distance consistent with the permit and conditions? Y ☐ N ☐

18. Was permittee advised that they must notify PPQ, BRS, and State Plant Regulatory Officials 21 calendar days before the anticipated harvest, and 21 days before cleaning dedicated equipment for return to general use to schedule inspections? Y ☐ N ☐

19. Report contains a significant deficiency Y ☐ N ☐

Inspecting Officer Signature: _____
Printed Name: _____
Phone: _____ Location of PPQ Officer: _____
Names and Affiliation of Any Other Persons at the inspection: _____

The signed original of this report was furnished to Juan Roman, APHIS, BRS Y ☐ N ☐

Inspection Reporting:
Report due 5 business days after inspection.
Use cover page to report violations.
Report deficiencies within 24 hrs to Regional Biotechnologist and Compliance Officer.

<p><i>Please fax/ email completed worksheet to:</i> Ralph Stoaks, Regional Biotechnologist 2150 Centre Ave. Bldg. B, 3E10 Ft. Collins, CO 80526 Phone: 970-494-7573 Fax: 970-494-7576 Email: ralph.d.stoaks@aphis.usda.gov</p>	<p><i>Please FedEx original worksheet to:</i> Juan Roman, Chief Biotechnology Program Operations 4700 River Road, Unit 147, 5B53 Riverdale, MD 20737 Phone: 301-734-0029</p>
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Remind cooperator of the following:

1) Federal Register Notice of March 10, 2003 stipulates that No Food or Feed Crops can be Grown or Harvested on field test site and fallow zone during the growing season for the test crop.

2) In case of accidental or unauthorized release, FR Notice stipulates that no food or feed crops can be grown or harvested on field test site and fallow zone during post-season monitoring period unless specific authorization to do so has been obtained from APHIS, BRS.

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FIGURE 8-21: Pharmaceutical/Industrial Release Report Worksheet, Page 2 of 3

- 3) PPQ, BRS, and State Plant Regulatory Officials must be notified in case of accidental or unauthorized release (e.g., seed loss, theft or vandalism, volunteer plants that are allowed to flower during the monitoring period,) notification must be made (within 24 hrs) to APHIS. Contact APHIS BRS Deputy Administrator's office, (301) 734-7324 or -5745, or (202) 720-4383 and indicate that you wish to report accidental release to BRS Regulatory Division Director.
- 4) PPQ, BRS, and State Plant Regulatory Officials must be notified at least 21 calendar days before cleaning dedicated equipment for return to general use to schedule inspections.
- 5) A volunteer monitoring report must be submitted within 3 months after the end of the monitoring period.

Revised
06/28/04

FIGURE 8-22: Pharmaceutical/Industrial Release Report Worksheet, Page 3 of 3

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Pharmaceutical/Industrial Flowering Report Worksheet

When completed, this is an Internal PPQ Document

Permit Number: _____ Crop: _____

Organization/Company: _____

Responsible Applicant: _____

Cooperator Contact Person: _____ Phone: _____

Location & GIS/ GPS Coordinates: _____

Type of location: Farm ☐ Nursery ☐ Other (describe) _____

Date of Inspection _____

1. Cooperator had a copy of permit conditions? Y ☐ N ☐

2. Was site size as stated in the permit? Y ☐ N ☐

3. Was site location according to permit? Y ☐ N ☐

4. Was physical security sufficient? Y ☐ N ☐

5. Was acreage according to permit? Y ☐ N ☐

6. Was fallow zone without food or feed crops? Y ☐ N ☐

7. What was on each side of test plot? Y ☐ N ☐

North _____

East _____

South _____

West _____

8. Was a 50 ft. perimeter fallow zone around crop? Y ☐ N ☐

9. Was a site map obtained or drawn by you for reference? Y ☐ N ☐

10. Was physical isolation distance according to permit? Y ☐ N ☐

11. Was dedicated equipment/machinery cleaned after use? Y ☐ N ☐

12. If corn pollen flow is controlled by bagging the tassels, was the isolation distance from other corn at least 2,640 feet? N/A ☐ Y ☐ N ☐

13. If corn pollen flow was controlled by placing bags around corn tassels, were bags in place? N/A ☐ Y ☐ N ☐

14. If controlled pollination was used, was de-tasseling completed? N/A ☐ Y ☐ N ☐

15. If volunteers are present and are the same or sexually compatible to the transgenic crop grown, indicate flowering stage: has occurred ☐ is occurring ☐ is just about to occur ☐

If corn tassels are bagged (question #12) and either #13, or #14 are negative (NO), or if #15 is checked, document with GPS & digital photos and IMMEDIATELY NOTIFY THE APHIS BRS REGULATORY DIVISION DIRECTOR for guidance on further action (301) 734-7324 or -5745, or (202) 720-4383.

16. Was temporal isolation (28 days) used? Y ☐ N ☐

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FIGURE 8-23: Pharmaceutical/Industrial Flowering Report Worksheet, Page 1 of 2

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17. Did applicant have a designated equipment cleaning area? Y ☐ N ☐

18. Were sexually compatible plants out of pollination distance? Y ☐ N ☐

19. Was total acreage of site furnished by 28 days after planting? Y ☐ N ☐

Report contains a significant deficiency Y ☐ N ☐

Inspecting Officer Signature: _____ Printed Name: _____

Phone: _____

Location of PPQ Officer: _____

Names and Affiliation of Any Other Persons at the inspection: _____

The signed original of this report was furnished to Juan Roman, APHIS, BRS Y ☐ N ☐

Inspection Reporting:

Report due 5 business days after inspection.

Use cover page to report violations.

Report deficiencies within 24 hrs to Regional Biotechnologist and Compliance Officer.

<p><i>Please fax/ email completed worksheet to:</i></p> <p><i>Ralph Stoaks, Regional Biotechnologist</i></p> <p><i>2150 Centre Ave. Bldg. B, 3E10</i></p> <p><i>Ft. Collins, CO 80526</i></p> <p><i>Phone: 970-494-7573 Fax: 970-494-7576</i></p> <p><i>Email: ralph.d.stoaks@aphis.usda.gov</i></p>	<p><i>Please FedEx original worksheet to:</i></p> <p><i>Juan Roman, Chief Biotechnology Program Operations</i></p> <p><i>4700 River Road, Unit 147, 5B53</i></p> <p><i>Riverdale, MD 20737</i></p> <p><i>Phone: 301-734-0029</i></p>
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Remind cooperator of the following:

- 1) Federal Register Notice of March 10, 2003 stipulates that No Food or Feed Crops can be Grown or Harvested on field test site and fallow zone during the growing season for the test crop.
- 2) In case of accidental or unauthorized release, FR Notice stipulates that no food or feed crops can be grown or harvested on field test site and fallow zone during post-season monitoring period unless specific authorization to do so has been obtained from APHIS, BRS.
- 3) PPQ, BRS, and State Plant Regulatory Officials must be notified in case of accidental or unauthorized release (e.g., seed loss, theft or vandalism, volunteer plants that are allowed to flower during the monitoring period,) notification must be made (within 24 hrs) to APHIS. Contact APHIS BRS Deputy Administrator's office, (301) 734-7324 or -5745, or (202) 720-4383 and indicate that you wish to report accidental release to BRS Regulatory Division Director.
- 4) PPQ, BRS, and State Plant Regulatory Officials must be notified at least 21 calendar days before cleaning dedicated equipment for return to general use to schedule inspections.
- 5) A volunteer monitoring report must be submitted within 3 months after the end of the monitoring period.

Revised 02/02/04

FIGURE 8-24: Pharmaceutical/Industrial Flowering Report Worksheet, Page 2 of 2

Pharmaceutical/Industrial Harvest Report Worksheet

When completed, this is an Internal PPQ Document

Permit Number: _____ Crop: _____

Organization/Company: _____

Responsible Applicant: _____

Cooperator Contact Person: _____ Phone: _____

Location & GIS/ GPS Coordinates: _____

Type of location: Farm ☐ Nursery ☐ Research ☐ Other (describe) _____

Date of Inspection _____

Site information: Check records and facilities and verify the following

1. Cooperator had copy of permit conditions Y ☐ N ☐
2. Names and dates of person performing the planting are recorded Y ☐ N ☐
3. Was dedicated planting equipment was used Y ☐ N ☐
4. Date of PPQ notice of harvest Y ☐ N ☐
5. How was crop harvested?

6. Describe method of disposal of regulated material (seeds, plant debris, plant parts, fruits, flowers, tubers, etc.)

7. Was dedicated harvest equipment cleaned of seed & plant material at site? Y ☐ N ☐
8. Was dedicated harvest equipment used and cleaned at special cleaning area as per protocol? Y ☐ N ☐
9. What was found on each side of planting site? Y ☐ N ☐
10. Was a 50 ft. perimeter fallow zone around the site? Y ☐ N ☐
11. Was a site map obtained or drawn by you for reference? Y ☐ N ☐
12. Is the reproductive isolation distance consistent with the permit? Y ☐ N ☐
13. Were seed cleaned and dried according to permit protocols? Y ☐ N ☐
14. Did records contain: dates, times, names, harvest dates, etc.? Y ☐ N ☐
15. Is there a secure, dedicated seed storage area or facility? Y ☐ N ☐
16. No volunteer crop plants were detected in the harvest site, fallow area or isolation zone Y ☐ N ☐

If No: # of volunteers found _____ Plant Name _____

Location Found: Site ☐ Fallow ☐ Isolation zone ☐

Report contains a significant deficiency Y ☐ N ☐

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FIGURE 8-25: Pharmaceutical/Industrial Harvest Report Worksheet, Page 1 of 2

Inspecting Officer Signature: _____ Printed Name: _____
 Phone: _____
 Location of PPQ Officer: _____
 Names and Affiliation of Any Other Persons at the inspection:

The signed original of this report was furnished to Juan Roman, APHIS, BRS Y ☐ N ☐

Inspection Reporting:
 Report due 5 business days after inspection.
 Use cover page to report violations.
 Report deficiencies within 24 hrs to Regional Biotechnologist and Compliance Officer.

Please fax/ email completed worksheet to: Ralph Stoaks, Regional Biotechnologist 2150 Centre Ave. Bldg. B, 3E10 Ft. Collins, CO 80526 Phone: 970-494-7573 Fax: 970-494-7576 Email: ralph.d.stoaks@aphis.usda.gov	Please FedEx original worksheet to: Juan Roman, Chief Biotechnology Program Operations 4700 River Road, Unit 147, 5B53 Riverdale, MD 20737 Phone: 301-734-0029
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Remind cooperator of the following:

- 1) Federal Register Notice of March 10, 2003 stipulates that No Food or Feed Crops can be Grown or Harvested on field test site and fallow zone during the growing season for the test crop.
- 2) In case of accidental or unauthorized release, FR Notice stipulates that no food or feed crops can be grown or harvested on field test site and fallow zone during post-season monitoring period unless specific authorization to do so has been obtained from APHIS, BRS.
- 3) PPQ, BRS, and State Plant Regulatory Officials must be notified in case of accidental or unauthorized release (e.g., seed loss, theft or vandalism, volunteer plants that are allowed to flower during the monitoring period,) notification must be made (within 24 hrs) to APHIS. Contact APHIS BRS Deputy Administrator's office, (301) 734-7324 or -5745, or (202) 720-4383 and indicate that you wish to report accidental release to BRS Regulatory Division Director.
- 4) PPQ, BRS, and State Plant Regulatory Officials must be notified at least 21 calendar days before cleaning dedicated equipment for return to general use to schedule inspections.
- 5) A volunteer monitoring report must be submitted within 3 months after the end of the monitoring period.

Revised
6/25/04

FIGURE 8-26: Pharmaceutical/Industrial Harvest Report Worksheet, Page 2 of 2

Pharmaceutical/Industrial Post-Harvest and Volunteer Monitoring Report Worksheet <i>When completed, this is an Internal PPQ Document</i>		
Permit Number: _____	Crop: _____	
Organization/Company: _____		
Responsible Applicant: _____		
Cooperator Contact Person: _____	Phone: _____	
Location & GIS/ GPS Coordinates: _____		
Type of location: Farm <input type="checkbox"/>	Greenhouse <input type="checkbox"/>	Other (describe) _____
Date of Inspection _____		
Cooperator had a copy of permit conditions?	Y <input type="checkbox"/>	N <input type="checkbox"/>
Site Security & Post Harvest Activities		
1. Was site security as stated in the permit?	Y <input type="checkbox"/>	N <input type="checkbox"/>
2. Do records indicate the quantity and current location of seed harvested?	Y <input type="checkbox"/>	N <input type="checkbox"/>
3. What was total quantity of harvested seed or plant material?	Y <input type="checkbox"/>	N <input type="checkbox"/>
4. Was stored seed secured in a locked, restricted, dedicated facility?	Y <input type="checkbox"/>	N <input type="checkbox"/>
5. Was dedicated equipment used to clean, dry or process transgenic seed or plant material?	N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>
6. Were these performed according to approved permit SOPs to minimize loss and spillage?	Y <input type="checkbox"/>	N <input type="checkbox"/>
7. If seed was shipped off-site, do records indicate that it was received at the intended destination, and that transportation equipment was cleaned according to an APHIS-approved SOP ?	N/A <input type="checkbox"/>	Y <input type="checkbox"/> N <input type="checkbox"/>
Crop Devitalization & Volunteer Monitoring		
8. Were records kept on how the test site has been managed and monitored for volunteers, e.g., irrigation, monitoring dates, number of volunteers found, actions taken, and person responsible?		
	Y <input type="checkbox"/>	N <input type="checkbox"/>
9. Number of volunteers found in last season's field test site or fallow zone _____		
Plant Name _____	N/A <input type="checkbox"/>	
10. If the volunteers are the same as or sexually compatible to the transgenic crop grown the previous season(s), indicate flowering: has occurred <input type="checkbox"/> is occurring <input type="checkbox"/> is about to occur <input type="checkbox"/>		
Revised 06/25/04		

FIGURE 8-27: Pharmaceutical/Industrial Post-Harvest and Volunteer Monitoring Report Worksheet, Page 1 of 2

Request to be walked through the delivery process to ensure containment

Draw a floor plan of facility if one is not available to show storage area and/or use digital camera to document any items of significance. Please send digital photos by e-mail (Optional and attached separately)

Additional comments:

APHIS Official Signature and Date

Company Representative and Date

<p><i>Please fax/ email completed worksheet to:</i></p> <p><i>Ralph Stoaks, Regional Biotechnologist</i></p> <p><i>2150 Centre Ave. Bldg. B, 3E10</i></p> <p><i>Ft. Collins, CO 80526</i></p> <p><i>Phone: 970-494-7573 Fax: 970-494-7576</i></p> <p><i>Email: ralph.d.stoaks@aphis.usda.gov</i></p>	<p><i>Please FedEx original worksheet to:</i></p> <p><i>Juan Roman, Chief Biotechnology Program Operations</i></p> <p><i>4700 River Road, Unit 147, 5B53</i></p> <p><i>Riverdale, MD 20737</i></p> <p><i>Phone: 301-734-0029</i></p>
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FIGURE 8-28: Pharmaceutical/Industrial Post-Harvest and Volunteer Monitoring Report Worksheet, Page 2 of 2

Facility Inspection Checklist for Containment of Genetically Engineered Organism	
When completed, this is an Internal PPQ Document, Contains CBI	
In Cover letter advise if Facility was in compliance and all questions must be answered	
Permit Number:	Date of Inspection:
Address of Facility	Responsible Person (Applicant)
Telephone: ()	Telephone: ()
Location of all Facilities Covered by this Inspection	
Building Name:	
Room/Laboratory Number:	
Growth Chamber Identification:	
Greenhouse or other Identification:	
RESEARCH QUALIFICATIONS AND GENERAL BACKGROUND	
1. Does this facility operate under the National Institutes of Health (NIH) Recombinant Advisory Committee (RAC) recombinant-DNA (r-DNA) guidelines?	
Yes <input type="checkbox"/> No <input type="checkbox"/>	
2. Is there a written policy regarding handling of r-DNA at this establishment?	
Yes <input type="checkbox"/> No <input type="checkbox"/>	
3. Who is the chair person of the local Institutional Biosafety Committee (IBC)?	
Name and Title	
4. Who is the scientist who will conduct the research?	
Name and Title	
5. Is the scientist who is conducting the research the permit applicant?	
Yes <input type="checkbox"/> No <input type="checkbox"/>	
6. What other scientists and technicians will be working on the research? Describe in a general way, their experience and qualifications.(i.e., give names, years experience)	
7. Do researchers and laboratory technicians practice and adhere to the NIH guidelines?	
Yes <input type="checkbox"/> No <input type="checkbox"/>	
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FIGURE 8-29: Facility Inspection Checklist for Containment of Genetically Engineered Organism, Page 1 of 1

FACILITY PHYSICAL DESIGN AND SECURITY		
8. Provide short description of how regulated article is physically marked and identified in the laboratory, growth chamber and greenhouse. Provide floor plan and / or map of facilities if possible.		
9. Is the general area secure from public access?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	If not please explain in cover letter
10. A. Is the general area secured from unauthorized personnel?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	If not please explain in cover letter
B. Can individual laboratories be locked?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
C. Is there at least one sign posted on the facility door stating that a regulated genetically engineered organism is present?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
D. Is no, when will a sign be installed? Installation DATE: _____		
11. Who is allowed in the research area?		
Cleaning Personnel	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Trade Persons	Yes <input type="checkbox"/>	No <input type="checkbox"/>
Others	Yes <input type="checkbox"/>	No <input type="checkbox"/>
12. How distant from each other are the germination laboratories, growth chamber and greenhouses? Be specific.		
13. What kind of records, log, or inventory are maintained regarding receipt, increase and destruction of regulated articles?		
HANDLING OF MATERIAL- GENERATION		
14. A. Is there a cabinet(s) or locker(s) to store seeds, plant material, tissue culture, etc?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
B. If yes, does it have a lock?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
C. Is the storage container identified with placards as containing a genetically engineered organism?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
D. If no, when will a sign be installed? Installation DATE: _____		
15. Where will seeds, tissue cultures, plant material, etc., be grown or germinated?		
16. What medium will be used for seed germination? (e.g. germination paper, perlite, or sand)		
17. Is there any danger of seeds, tissue cultures, plant material, etc., being lost during this germination process, or of ungerminated seed being transferred into subsequent research stages?		
18. Are there water cracks or irregular surfaces in the germination laboratory that could trap seeds?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
19. Are there water drains in the laboratory?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
20. Are the drains screened?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	If yes, what is the size of the screen?
21. Does the drain system enter into a special waste trap?		
Yes <input type="checkbox"/>	No <input type="checkbox"/>	
22. How will the germinated seed be moved to the growth chamber?		
Revised 06/28/04		

FIGURE 8-30: Facility Physical Design and Security, Page 1 of 4

23. How will Petri dishes, tissue cultures, spores, plant material, ect., be moved from the laminar flow hood to the growth chamber?

24. How will the regulated articles be kept separated from other organisms?

25. Does the growth chamber have access by authorized personnel only?
Yes ☐ No ☐

26. Describe the growth chamber.
Lab top ☐ Walk in ☐ Built on site ☐ Other ☐

27. Will the material be grown with any other plant materials in the same chamber?
Yes ☐ No ☐ If yes, name the types of plants.

28. How will genetically engineered plants and/or containers be physically marked?

29. Does the growth chamber have water drains?
Yes ☐ No ☐
If so, can they be screened?
Yes ☐ No ☐

30. Does the drain system enter into a special waste trap?
Yes ☐ No ☐

31. Where is the autoclave or incinerator in relation to the growth chamber?

32. Can the growth chamber be locked and separated from other growth chamber(s)?
Yes ☐ No ☐

33. How will the material be transferred to the greenhouse?

HANDLING OF MATERIAL- GREENHOUSE

35. What is the name of the greenhouse manager?

36. Is the greenhouse accessed by authorized personnel only?
Yes ☐ No ☐

37. A. Does the greenhouse have a double door entry system?
Yes ☐ No ☐
B. Is the greenhouse entry through a "Head-House"?
Yes ☐ No ☐

38. A. Do the greenhouse doors have locks?
Yes ☐ No ☐
B. Is there a rear exit door?
Yes ☐ No ☐

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FIGURE 8-31: Facility Physical Design and Security, Page 2 of 4

39. What type of greenhouse?
Glass ☐ Lexan ☐ Plastic ☐ Poly ☐
Screen ☐ Other ☐
If screen, what size mesh used? If poly, what thickness?

40. What are the approximate outside dimensions of the greenhouse(s)?

41. A. Do the roof vents open?
Yes ☐ No ☐
B. Is the roof vent opens, is it screened?
Yes ☐ No ☐
What size is the screen mesh?

42. What kind of floor does the greenhouse have?
Concrete ☐ Gravel ☐ Packed Dirt ☐ Other(Explain)

43. Does the greenhouse have water drains? Describe

Do they enter into special waste trap?
Yes ☐ No ☐

44. A. Does the greenhouse have black light traps for vectors?
Yes ☐ No ☐
B. Does the greenhouse have "Sticky Board" traps for vectors?
Yes ☐ No ☐
C. Does the greenhouse have other kinds of vector traps? Describe

45. How will the plants be grown in the greenhouse?
On Benches ☐ In Flats ☐ In Pots ☐ Other(describe)

46. Will there be physical markers on each plant indicating that the plants are genetically engineered?
Yes ☐ No ☐

47. Where is the autoclave or incinerator in relation to where the greenhouse plants will be grown?

48. Are there any openings in the greenhouse through which animals and pollinating insects could enter?
Yes ☐ No ☐

49. How will the regulated articles be kept separate from other organisms?

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FIGURE 8-32: Facility Physical Design and Security, Page 3 of 4

GENERAL CONSIDERATION	
What kind of "Spill" responses action plan/equipment is available for items spilled in transit between labs, chambers, and greenhouses? If regulated items are carried in contained vessels should not be a problem.	
<div></div>	
<div></div>	
Are any other similar plants growing in the area, either on the facility grounds or outside of the facility grounds?	
<div></div>	
<div></div>	
You should look for any other factor which may influence the handling of seed plants and that may have an effect on containment or risk.	
<div></div>	
<div></div>	
Inspect for other specific conditions as stipulated on the permit.	
Inspecting Officer Signature: _____	Printed Name: _____
Phone: _____	
Location of PPQ Officer: _____	
Names and Affiliation of Any Other Persons at the inspection: _____	

The signed original of this report was furnished to Juan Roman, APHIS, BRS	
Y <input type="checkbox"/>	N <input type="checkbox"/>
Inspection Reporting:	
Report due 10 business days after inspection.	
Use cover page to report violations.	
Report deficiencies within 24 hrs to Regional Biotechnologist.	
<i>Please FedEx original worksheet to:</i>	
<i>Juan Roman, Chief Biotechnology Program Operations</i>	
<i>4700 River Road, Unit 147, 5B53</i>	
<i>Riverdale, MD 20737</i>	
<i>Phone: 301-734-0029</i>	
<i>Please fax/ email completed worksheet to:</i>	
<i>Ralph Stoaks, Regional Biotechnologist</i>	
<i>2150 Centre Ave. Bldg. B, 3E10</i>	
<i>Ft. Collins, CO 80526</i>	
<i>Phone: 970-494-7573 Fax: 970-494-7576</i>	
<i>Email: ralph.d.stoaks@aphis.usda.gov</i>	
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FIGURE 8-33: Facility Physical Design and Security, Page 4 of 4

**Storage Facility Inspection Checklist
for Containment of Genetically Engineered Organisms
Not Intended for Food or Feed**

When completed, this is an Internal PPQ Document

Instructions:

- 1) Complete the checklist and answer questions appropriately, Yes, No, or N/A. Please explain all the N/A's with a answer on a cover page
- 2) No checklist can be tailored to fit all different types of storage facilities. Examine the facility with an eye for security and ways that the transgenic plant materials are kept separated from plant material that is intended for food or feed.

When setting up the inspection request two items in advance:

- Standard operating Procedures
- Inventory (See below)

3) Many applicants have or are developing Standard Operating Procedures (SOPs), **request they send you a copy of all Standard Operating Procedures (SOPs)**. Review the SOPs before the inspection, to identify items that you should include in your inspection. Determine if they are following all of their SOPs correctly. The space at the end of the checklist provides room any additional comments or items included in your inspection.

4) Request a copy of the inventory of stock.

1. Date of Inspection _____
2. Inspector (Print) _____
3. Company and Address of Facility _____
4. Permit Number _____
5. Telephone Number of Facility Contact Person _____
6. Person(s) present during the inspection and affiliation

7. Can the facility be locked securely during normal business hours? Y ☐ N ☐ N/A ☐
8. Is facility locked when authorized staff is not present? Y ☐ N ☐ N/A ☐

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FIGURE 8-34: Storage Facility Inspection Checklist for Containment of Genetically Engineered Organisms Not Intended for Food or Feed, Page 1 of 3

9. Is access to the facility restricted to research and administrative staff ?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
10. Were you able to obtain a copy of the current inventory?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
11. Is a copy of the current inventory included in the report?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
<i>(Records should include transgene and the year produced)</i>			
12. Does a random check of the inventory insure it's accurate and up to date?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
13. Was rodent control maintained?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
14. Were records kept of item 13 above?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
15. Were containers clearly labeled?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
16. Were storage containers designed to prevent leakage of seeds?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
17. Containers were non-leaking	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
18. Containers had label to show transgenic material	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
19. Was the plant material transferred to a storage facility?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
20. Will the plant material be shipped in a manner to insure containment?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
21. Check the final disposition of the material			
Shipped <input type="checkbox"/>	devitalized <input type="checkbox"/>	stored <input type="checkbox"/>	frozen <input type="checkbox"/>
22. Was the material 100% devitalized? (Explain as appropriate i.e., if a spill was found)	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
23. Were employees aware that the seed is not intended for food or feed?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>
24. Was there a written policy to educate non-research staff on seed for food/feed?	Y <input type="checkbox"/>	N <input type="checkbox"/>	N/A <input type="checkbox"/>

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FIGURE 8-35: Storage Facility Inspection Checklist for Containment of Genetically Engineered Organisms Not Intended for Food or Feed, Page 2 of 3

Request to be walked through the delivery process to ensure containment

Draw a floor plan of facility if one is not available to show storage area and/or use digital camera to document any items of significance. Please send digital photos by e-mail (Optional and attached separately)

Additional comments:

APHIS Official Signature and Date

Company Representative and Date

<p>Please fax/ email completed worksheet to:</p> <p>Ralph Stoaks, Regional Biotechnologist</p> <p>2150 Centre Ave. Bldg. B, 3E10</p> <p>Ft. Collins, CO 80526</p> <p>Phone: 970-494-7573 Fax: 970-494-7576</p> <p>Email: ralph.d.stoaks@aphis.usda.gov</p>	<p>Please FedEx original worksheet to:</p> <p>Juan Roman, Chief Biotechnology Program Operations</p> <p>4700 River Road, Unit 147, 5B53</p> <p>Riverdale, MD 20737</p> <p>Phone: 301-734-0029</p>
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